

## **Amend HB18-1155 to Uphold FDA Regulations**

“The procurement or use of solid filiform needles or any instrument regulated by the FDA as an acupuncture needle is not within the scope of practice of physical therapists.”

**“It is a violation of Federal law when unqualified practitioners of acupuncture, such as physical therapists, purchase, possess, or use an acupuncture needle.”**

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President's Council - American Association of Colleges  
Dr. 2001 12/20/01

regulatory staff

regulatory staff, such as physical therapists, nurses, doctors, or use as

It is a violation of Federal law when unlicensed practitioners of

regulatory staff is not within the scope of practice of physical therapists

The prohibition of use of such unlicensed persons or any institution regulated by the FDA as an

## Amend HB 18-1122 to Clarify FDA Regulations

## Contents:

Acupuncture vs Dry Needling.....	Page 3
Training Requirements.....	Page 4
Adverse Events.....	Page 5
3 Facts About Dry Needling.....	Page 6
FDA Regulations of Needles.....	Page 10
AMA Dry Needling Position.....	Page 12
AAPM&R Position Statement.....	Page 13
AAMA Position Statement.....	Page 14
DORA Policy on Education.....	Page 16
Examples of “Dry Needling.....	Page 17

# Acupuncture vs. Dry Needling

The same tool

In the same location

Used in the same way

To achieve the same results.

According to 12-33-102 (1) ""Acupuncture" means the puncture of the skin with fine needles for diagnostic and therapeutic purposes."

Dry Needling is the insertion of fine needling for diagnostic and therapeutic purposes and is therefore by definition, Acupuncture.

## FDA Regulations:

According to the FDA regulation regarding acupuncture needles, "FDA believes that information for use, including: Indications, effects, routes, methods, and frequency and duration of administration; and any hazards, contraindications, side effects, and precautions are commonly known to qualified practitioners of acupuncture. Therefore, under § 801.109(c), such indications do not need to be on the dispensing packaging, **but sale must be clearly restricted to qualified practitioners of acupuncture as determined by the States.**" (emphasis added)

Rule 10:

(A) 1. The Director recognizes that "Injection therapy" is the stimulation of acupuncture points, including trigger points (historically known as "AHSHI" points), by the injection of saline, sterile herbs, vitamins, minerals, homeopathic substances, glucose, lidocaine, procaine, and sarapin, or other similar substances specifically manufactured for nonintravenous injection by means of hypodermic needles.

**ALL** solid filiform needles are regulated by the FDA as Acupuncture needles. Physical therapists do not qualify as practitioners of Acupuncture.

# Acupuncture vs. Dry Needling

To achieve the same results  
Used in the same way  
in the same location  
the same tool

According to 15-33-102 (1) "Acupuncture" means the puncture of the skin with fine needles for diagnostic and therapeutic purposes."  
Dry Needling is the insertion of fine needles for diagnostic and therapeutic purposes and is therefore by definition Acupuncture.

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Rule 10:

(A) F. The Director recognizes that "injection therapy" is the stimulation of acupuncture points, including trigger points (historically known as "Ashi" points) by the insertion of sterile, sharp, or other similar substances specifically manufactured for nonintravenous injection by means of hypodermic needles, metallic herbs, vitamins, minerals, homeopathic substances, glucose, fibroblast growth factor,

ALL solid filament needles are regulated by the FDA as acupuncture needles. Physical therapists do not qualify as practitioners of acupuncture.

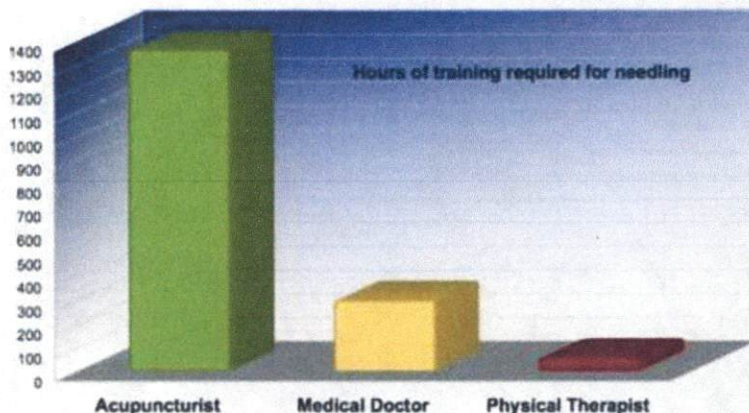
**Required training for Acupuncturists:**

Didactic Classroom Instruction: 705 Hours

Supervised Clinical Hours: 660

BioMedicine: 450 Hours

Ethics / Practice Management: 90 Hours



**Rule 211:**

(A) Dry needling (also known as Trigger Point Dry Needling) is a physical intervention that uses a filiform needle to stimulate trigger points, diagnose and treat neuromuscular pain and functional movement deficits; is based upon Western medical concepts; requires an examination and diagnosis, and treats specific anatomic entities selected according to physical signs. Dry needling does not include the stimulation of auricular or distal points.

(D) 2. have successfully completed a dry needling course of study that consists of a minimum of 46 hours of in-person (i.e. not online) dry needling training.

**Policy Adopted March 21, 2014**

If the required course of at least 46 hours of in-person dry needling training is broken up into more than one part, then a licensed physical therapist is permitted the limited practice of dry needling once he or she has completed each part of the training as long as such practice is confined to the scope of the training already successfully completed, and with the understanding that all parts of the coursework will be successfully completed within 2 years of the start date of the course.

**American Medical Association:**

“Dry needling is indistinguishable from acupuncture.”

- "Our AMA recognizes dry needling as an invasive procedure and maintains that dry needling should only be performed by practitioners with standard training and familiarity with routine use of needles in their practice, such as licensed medical physicians and licensed acupuncturists."

**American Academy of Medical Acupuncture:**

“To include dry needling into the scope of practice by physical therapists is unnecessarily to expose the public to serious and potentially hazardous risks.”

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American Academy of Physical Therapists:

... needling techniques...  
... with routine use of needles in their practice and as licensed medical practitioners and  
... needling should only be performed by practitioners with standard training and certification.  
• The APTA recognizes dry needling as an invasive procedure and maintains that dry  
... dry needling is indistinguishable from acupuncture.

American Medical Association:

... the course  
... that all parts of the curriculum will be successfully completed within 2 years of the start date of  
... confined to the scope of the training and will be successfully completed and will be successful in  
... needling once per or the use completed over part of the training program as each course is  
... more than one hour from a licensed physical therapist is permitted the number in case of dry  
... if the required course of at least 40 hours of in-person dry needling training is provided to  
... Board. Adopted March 21, 2014

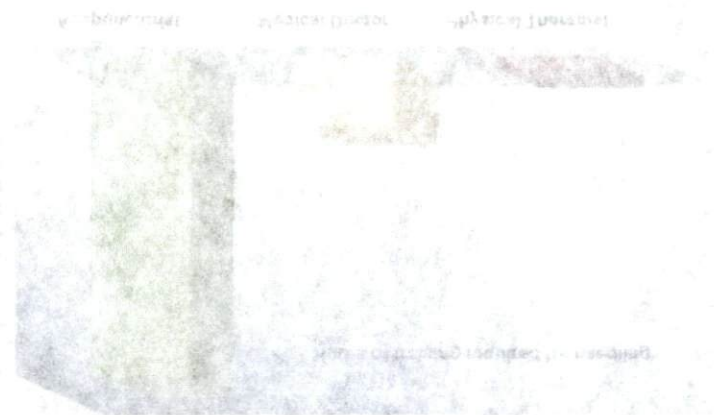
... of 40 hours of in-person (not online) dry needling training  
(1) 5. have successfully completed a dry needling course of study that consists of a minimum

... needling does not include the elimination of anatomy or other basic  
... and diagnosis and basic scientific anatomy courses selected according to physical signs, (2)  
... functional movement deficits, is based upon a clinical medical concepts, contains an examination  
... uses a dry needling to stimulate trigger points, reflexes and local anesthetic, both and  
(4) Dry needling (also known as trigger point dry needling) is a physical intervention that

Board 2111

- Basic Anatomy and Physiology, 120 Hours
- Medical Terminology, 120 Hours
- Physiology, 120 Hours
- Physical Therapy, 120 Hours

Required Training for Acupuncture:



## Adverse Events:

- March 25 2013 – FDA Complaint and collapsed lung from dry needling at the University of Colorado hospital
- Nov 29 2013 Winter Olympian Torin Yater-Wallace suffered a collapsed lung by a physical therapist
- Altitude Physical therapy puncture the lung of a female patient in 2014
- June 2013 Pneumothorax at Aspen Valley Hospital from dry needling
- February 20 2016 collapsed lung from dry needling at Foothills hospital in Boulder
- Duane Fenton, PA-C at Western Orthopedics had to surgically remove an acupuncture needle from a patient's shoulder after a physical therapist broke the needle off in the patient's bone
- A physical therapist punctured a patient's right lung with an acupuncture needle, causing damage to the lung that led to a pneumothorax. She was hospitalized and underwent treatment for the pneumothorax.
- A physical therapist punctured a patient's left lung with an acupuncture needle, causing damage to the lung that led to a pneumothorax. She was hospitalized and underwent treatment for the pneumothorax.
- A physical therapist punctured a patient's lung with an acupuncture needle, causing damage to the lung that led to a pneumothorax. She required surgery to treat the pneumothorax and was hospitalized for three days.
- A physical therapist was performing dry needling on a patient's hip when the handle of the acupuncture needle broke off, leaving the shaft of the acupuncture needle lodged in the hip. This was probably due to the physical therapist using excessive force when manipulating (rotating or pistoning) the acupuncture needle. She was hospitalized and underwent surgery to remove the shaft of the acupuncture needle.
- A physical therapist performed dry needling on a patient's calf while failing to adhere to basic infection prevention and control practices, resulting in the patient developing a calf infection. She required "intravenous therapy and two surgical procedures" to treat the calf infection.

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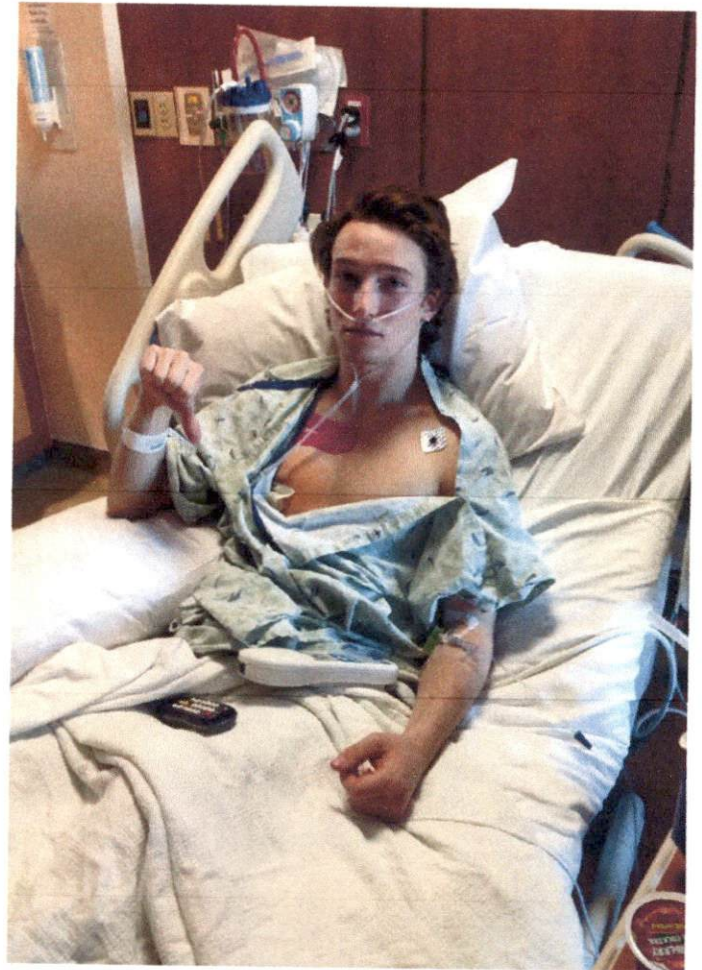
# Top 3 Facts You REALLY Need to Know about Dry Needling

## 1. Dry needling is acupuncture.

Originating in ancient China, acupuncture is a surgical operation (1-4) in which an acupuncture point (a specific muscle or connective tissue site) is punctured with an acupuncture needle (a fine needle) to cure, mitigate, treat, or prevent disease or other conditions (1). Acupuncture is based on anatomy, physiology, and pathology (1,5-12).

Dry needling is acupuncture in which an acupuncture point that has become exquisitely tender, commonly known in the West as a trigger point, is punctured with an acupuncture needle to cure, mitigate, treat, or prevent disease or other conditions, especially musculoskeletal and connective tissue disorders, including musculoskeletal pain (1). An acupuncture point that has become exquisitely tender is identified by a flinch reaction on palpation (1).

Dry needling is not new. It was described in the first century BCE in the *Yellow Emperor's Inner Classic* (黃帝內經 [Huáng Dì nèi jīng]), the foundational text of Chinese medicine (1).



In this November 30, 2013 photo, 17-year-old professional freeskier Torin Yater-Wallace gives the thumbs-down sign from his hospital bed at St. Anthony Summit Medical Center in Frisco, Colorado, while recovering from surgery for a traumatic pneumothorax (an accumulation of air in the pleural cavity resulting from blunt or penetrating chest injury and causing lung collapse) that he suffered after a physical therapist punctured his right lung with an acupuncture needle. (Photo: @TorinWallace)

causing lung collapse) (13). She was treated for the traumatic pneumothorax at the emergency department of the Kaiser Permanente Zion Medical Center in San Diego, California (13). The traumatic pneumothorax required medical and surgical intervention (13).

### Colorado

**Case 1.** In November 2013, 17-year-old professional freeskier Torin Yater-Wallace suffered a penetrating right lung injury caused by a physical therapist performing dry needling (14-16). The penetrating right lung injury resulted in a traumatic pneumothorax (14-16). He was

## 2. Dry needling is unsafe when performed by unqualified practitioners of acupuncture, such as physical therapists.

As exposed by the Dry Needling Adverse Event Tracking System (DNAETS) case reports, dry needling is unsafe when performed by unqualified practitioners of acupuncture, such as physical therapists.

### Dry Needling Adverse Event Tracking System (DNAETS) Case Reports

#### California

**Case 1.** In January 2014, 31-year-old general manager Jamie Del Fierro suffered a penetrating left lung injury caused by a chiropractor performing dry needling (13). The penetrating left lung injury resulted in a traumatic pneumothorax (an accumulation of air in the pleural cavity resulting from blunt or penetrating chest injury and

# Top 3 Facts You REALLY Need to Know about Dry Needling



## 1. Dry needling is acupuncture

Acupuncture is a traditional Chinese medicine practice that has been used for thousands of years. It involves the insertion of thin needles into specific points on the body to stimulate the body's natural healing response. Dry needling, on the other hand, is a modern technique that uses thicker needles to target myofascial trigger points. While both techniques involve the insertion of needles, dry needling is based on Western medical principles, while acupuncture is based on traditional Chinese medicine.

Dry needling is a technique that uses thin needles to target myofascial trigger points. These points are areas of muscle that have become hyperirritable and can cause pain and dysfunction. Dry needling involves the insertion of needles into these points to stimulate the body's natural healing response. This can help to reduce pain and improve function. Dry needling is often used in conjunction with other physical therapy techniques, such as exercise and manual therapy.

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## 2. Dry needling is unsafe when performed by unqualified practitioners of acupuncture, and as physical therapists.

Acupuncture is a traditional Chinese medicine practice that has been used for thousands of years. It involves the insertion of thin needles into specific points on the body to stimulate the body's natural healing response. Dry needling, on the other hand, is a modern technique that uses thicker needles to target myofascial trigger points. While both techniques involve the insertion of needles, dry needling is based on Western medical principles, while acupuncture is based on traditional Chinese medicine. Dry needling is often performed by unqualified practitioners, which can be dangerous. Physical therapists who are not trained in dry needling should not perform this procedure.

## Dry Needling Adverse Event Tracking System (DNETS) Case Reports

California

Case 1: In January 2014, 31-year-old female patient presented with a 2-week history of right-sided weakness and numbness. She had a history of multiple sclerosis (MS) and was on chronic therapy. She had a recent MRI of the brain which showed a new lesion in the right parietal lobe. She was referred to physical therapy for evaluation and treatment. The physical therapist noted that the patient had a significant weakness in the right arm and leg. She was unable to lift her right arm and had difficulty walking. The physical therapist performed a physical examination and found that the patient had a significant weakness in the right arm and leg. She was unable to lift her right arm and had difficulty walking. The physical therapist performed a physical examination and found that the patient had a significant weakness in the right arm and leg. She was unable to lift her right arm and had difficulty walking.

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treated for the traumatic pneumothorax at the emergency department of the St. Anthony Summit Medical Center in Frisco, Colorado, and was admitted to that hospital on the same day. The traumatic pneumothorax required medical and surgical intervention (14). He was hospitalized for five days (14).

**Case 2.** In June 2015, 41-year-old clinical social worker Lisa Kerscher suffered a penetrating lung injury caused by a physical therapist performing dry needling (17). The penetrating lung injury resulted in a traumatic pneumothorax (17). She was treated for the traumatic pneumothorax at the emergency department of the Rose Medical Center in Denver, Colorado (17). The traumatic pneumothorax required medical intervention (17).

### Georgia

**Case 1.** In August 2015, 70-year-old Eva Campbell suffered a penetrating left lung injury caused by a physical therapist performing dry needling (18). The penetrating left lung injury resulted in a traumatic pneumothorax (18). She was treated for the traumatic pneumothorax at the emergency department of the Northeast Georgia Medical Center Gainesville in Gainesville, Georgia, and was admitted to that hospital on the same day (18). The traumatic pneumothorax required medical and surgical intervention (18). She was hospitalized for four days (18). However, she now has difficulty breathing (18).

### Maryland

**Case 1.** In October 2012, 24-year-old science teacher Emily Kuykendall suffered a penetrating nerve injury in her left leg caused by a physical therapist performing dry needling (19). The penetrating nerve injury in her left leg resulted in severe pain, numbness, and paresthesias (abnormal sensations, typically tingling or pricking ["pins-and-needles"]) (19). The severe pain, numbness, and paresthesias required medical intervention (19).

"[The severe pain, numbness, and paresthesias are] really taking a physical and emotional toll on me," Ms. Kuykendall wrote approximately three weeks after she was injured. "There is almost not a minute in the day that goes by that I wish that I had not gone to see [the physical therapist]" (19).

### North Carolina

**Case 1.** In December 2014, a female patient suffered a penetrating lung injury caused by a physical therapist

performing dry needling (20). The penetrating lung injury resulted in a traumatic pneumothorax (20). The traumatic pneumothorax required medical and surgical intervention (20).

**Case 2.** In February 2016, a female patient suffered a penetrating cervical spinal cord injury caused by a physical therapist performing dry needling (20). The penetrating cervical spinal cord injury resulted in severe pain, numbness, and paraparesis (partial paralysis of the lower limbs) (20). She was treated for the severe pain, numbness, and paraparesis at the emergency department of the WakeMed Cary Hospital in Cary, North Carolina, and was admitted to that hospital on the same day (20). The severe pain, numbness, and paraparesis required medical intervention (20). She was hospitalized for three days (20).

### Ohio

**Case 1.** In January 2016, 51-year-old Brenda Bierman suffered a penetrating right lung injury caused by a physical therapist performing dry needling (21). The penetrating right lung injury resulted in a traumatic pneumothorax (21). She was treated for the traumatic pneumothorax at the emergency department of the ProMedica Toledo Hospital in Toledo, Ohio, and was admitted to that hospital on the same day (21). The traumatic pneumothorax required medical and surgical intervention (21).

**Case 2.** In February 2016, 47-year-old Anong Pipatjarasgit suffered a penetrating thoracic spinal cord injury caused by a physical therapist performing dry needling (22). The penetrating thoracic spinal cord injury resulted in a traumatic spinal epidural hematoma (an accumulation of blood in the spinal epidural space resulting from blunt or penetrating spinal injury) (22). She was treated for the traumatic spinal epidural hematoma at the emergency department of the ProMedica Toledo Hospital in Toledo, Ohio, and was admitted to that hospital on the same day (22). The traumatic spinal epidural hematoma required medical and surgical intervention (22). After recovering from emergency surgical decompression and evacuation of the traumatic spinal epidural hematoma, she underwent extensive inpatient and outpatient rehabilitation (22). However, she now has permanent severe neurologic deficits, including paraparesis, sensory deficits, and bowel dysfunction, and has persistent severe back pain (22).

Case 1. In August 2017, 70-year-old Mrs Campbell suffered a peritumoural long tract injury caused by a physical therapist performing dry needling (8). The patient reported long tract injury resulting in a traumatic pneumothorax (18). She was treated for the traumatic pneumothorax at the emergency department of the Royal Victoria Hospital, Devon, UK. She was admitted to the hospital on the same day. The traumatic pneumothorax required medical intervention (19).

**Georgia**

Case 1. In August 2017, 70-year-old Mrs Campbell suffered a peritumoural long tract injury caused by a physical therapist performing dry needling (8). The patient reported long tract injury resulting in a traumatic pneumothorax (18). She was treated for the traumatic pneumothorax at the emergency department of the Royal Victoria Hospital, Devon, UK. She was admitted to the hospital on the same day. The traumatic pneumothorax required medical and surgical intervention (18). She was hospitalised for 10 days (18). Her work was affected as a result of the injury (18).

**Mississippi**

Case 1. In October 2018, 54-year-old Mrs Campbell suffered a peritumoural long tract injury in the left leg caused by a physical therapist performing dry needling (19). The patient reported long tract injury resulting in severe pain, numbness, and paresthesias (abnormal sensations, typically tingling, prickling, pins and needles) (19). The severe pain, numbness, and paresthesias required medical intervention (19). [The severe pain, numbness, and paresthesias are] not taking a physical and emotional toll on me" (20). Mrs Campbell wrote approximately three weeks after she was injured, "There is almost no moments in the day that goes by that I wish that I had not gone to see [the physical therapist]" (19).

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Case 2. In February 2016, a female patient suffered a peritumoural long tract injury caused by a physical therapist performing dry needling (21). The patient reported long tract injury resulting in severe pain, numbness, and paresthesias (abnormal sensations, typically tingling, prickling, pins and needles) (21). She was treated for the traumatic pneumothorax at the emergency department of the Royal Victoria Hospital, Devon, UK. She was admitted to the hospital on the same day. The severe pain, numbness, and paresthesias required medical and surgical intervention (21). She was hospitalised for 10 days (21).

**Ohio**

Case 1. In January 2016, a 45-year-old Mrs Bennett suffered a peritumoural long tract injury caused by a physical therapist performing dry needling (22). The patient reported long tract injury resulting in a traumatic pneumothorax (22). She was treated for the traumatic pneumothorax at the emergency department of the Royal Victoria Hospital, Devon, UK. She was admitted to the hospital on the same day. The traumatic pneumothorax required medical and surgical intervention (22).

Case 2. In February 2016, a 45-year-old Mrs Bennett suffered a peritumoural long tract injury caused by a physical therapist performing dry needling (22). The patient reported long tract injury resulting in a traumatic pneumothorax (22). She was treated for the traumatic pneumothorax at the emergency department of the Royal Victoria Hospital, Devon, UK. She was admitted to the hospital on the same day. The traumatic pneumothorax required medical and surgical intervention (22). After recovering from emergency surgical decompression and resection of the traumatic pneumothorax, the patient underwent extensive physical and occupational therapy (22). However, she still has permanent severe neurological deficits including paresthesias, sensory deficits, and bowel dysfunction and has persistent severe back pain (22).

## South Carolina

**Case 1.** In September 2014, a patient suffered a penetrating lung injury caused by a physical therapist performing dry needling (23). The penetrating lung injury resulted in a traumatic pneumothorax (23). The traumatic pneumothorax required medical and surgical intervention (23).

## Virginia

**Case 1.** In December 2013, a 50-year-old female patient suffered a penetrating right lung injury caused by a physical therapist performing dry needling (24). The penetrating right lung injury resulted in a traumatic pneumothorax (24). The traumatic pneumothorax required medical intervention (24). She was hospitalized for two days (24).

**Case 2.** In May 2015, a 30-year-old female patient suffered a penetrating right lung injury caused by a chiropractor performing dry needling (25). The penetrating right lung injury resulted in a traumatic pneumothorax (25). The traumatic pneumothorax required medical intervention (25).

**Case 3.** In Fall 2016, 23-year-old physical therapy student Wes Jenkins suffered a penetrating lung injury caused by a physical therapist performing dry needling (26). The penetrating lung injury resulted in a traumatic pneumothorax (26). The traumatic pneumothorax required medical and surgical intervention (26). He was hospitalized for four days (26).

It bears repeating: Dry needling is unsafe when performed by unqualified practitioners of acupuncture, such as physical therapists.

To report a serious dry needling adverse event, use the Dry Needling Adverse Event Reporting System (DNAERS) form at <https://www.acupuncturesafety.org/dry-needling-adverse-event-reporting-system-dnaers-form>. The National Center for Acupuncture Safety and Integrity (NCASI) will use the information as part of our legislative and administrative advocacy work.

3. It is a violation of Federal law when unqualified practitioners of acupuncture, such as physical

therapists, purchase, possess, or use an acupuncture needle.

An acupuncture needle is a restricted medical device under section 520(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. § 360j(e)) (27).

The U.S. Food and Drug Administration (FDA) has restricted the sale, distribution, and use of an acupuncture needle "to prescription use" (28). In addition, in order to ensure the safe and effective use of an acupuncture needle, FDA has further restricted the sale, distribution, and use of an acupuncture needle "to qualified practitioners of acupuncture as determined by the States" (29). Therefore, it is a violation of Federal law when unqualified practitioners of acupuncture, such as physical therapists, purchase, possess, or use an acupuncture needle (30).

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21. Bierman v. Ligan PT, No. G-4801-CI-201701167-000 (Ohio Common Pleas Court, Lucas County Jan. 13, 2017).
22. Pipatjarasgit v. ProMedica, No. G-4801-CI-201703351-000 (Ohio Common Pleas Court, Lucas County Jul. 14, 2017).
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27. See 21 U.S.C. § 360j(e); 21 CFR § 807.3(i); 21 CFR § 880.5580(b)(1); 21 CFR § 801.109; see also 61 Fed.Reg. 64616 (Dec. 6, 1996).
28. See 61 Fed.Reg. 64616 (Dec. 6, 1996); see also 21 CFR § 880.5580(b)(1); 21 CFR § 801.109; 21 U.S.C. § 360j(e); 21 CFR § 807.3(i).
29. See 61 Fed.Reg. 64616 (Dec. 6, 1996) (emphasis added); see also 21 CFR § 880.5580(b)(1); 21 CFR § 801.109; 21 U.S.C. § 360j(e); 21 CFR § 807.3(i).
30. See 21 U.S.C. §§ 331(a)-(c), (g), and (k); 21 U.S.C. §§ 352(q) and (r).

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The National Center for Acupuncture Safety and Integrity (NCASI) is an all-volunteer 501(c)(3) tax-exempt organization that works to protect patients from unqualified practitioners of acupuncture, such as physical therapists. We accomplish our mission through legislative and administrative advocacy.

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Therefore, a regulatory flexibility analysis as provided in Public Law 96-354, the Regulatory Flexibility Act, is not required.

*Paperwork Reduction Act*

This regulation imposes no reporting/recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: December 2, 1996.  
Shirley S. Chater,  
Commissioner of Social Security.

For the reasons set forth in the preamble, part 404, subpart P, chapter III of title 20 of the Code of Federal Regulations is amended as set forth below:

**PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950— )**

**Subpart P—[Amended]**

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)).

2. Appendix 1 to subpart P of part 404 is amended by revising item 1 of the introductory text before part A to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

\* \* \* \* \*

1. Growth Impairment (100.00):  
December 7, 1998.

\* \* \* \* \*

[FR Doc. 96-31037 Filed 12-5-96; 8:45 am]

BILLING CODE 4190-29-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 880**

[Docket Number 94P-0443]

**Medical Devices; Reclassification of Acupuncture Needles for the Practice of Acupuncture**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it is reclassifying acupuncture needles for the practice of acupuncture and substantially equivalent devices of this generic type from class III (premarket approval) into class II (special controls). FDA is also announcing it has issued an order in the form of a letter to the Acupuncture Coalition reclassifying acupuncture needles. This action is in response to petitions filed by the Acupuncture Coalition and in keeping with, but not dependent upon, the recommendation of FDA's Anesthesiology Devices Advisory Panel (the Panel). This action is being taken because the agency believes that there is sufficient information to establish that special controls will provide reasonable assurance of the safety and effectiveness of acupuncture needles.

**EFFECTIVE DATE:** December 6, 1996.

**FOR FURTHER INFORMATION CONTACT:** Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8879.

**SUPPLEMENTARY INFORMATION:** On December 6, 1995, FDA filed reclassification petitions from the Acupuncture Coalition, which includes representatives of the following manufacturers: Carbo (Mfg.), China; Hwa-To, China; Chung Wha, South Korea; Taki, South Korea; Dong Bang, South Korea; Tseng Shyh Co., Taiwan; HCD, France; Sedatelec, France; Seirin-Kasei (Mfg.), Japan; Ito Co., Japan; and Ido-No-Nippon-Sha, Japan, requesting reclassification of acupuncture needles from class III to class II. On March 29, 1996, FDA issued an order (Ref. 1) in the form of a letter, to the petitioners reclassifying acupuncture needles for the practice of acupuncture and substantially equivalent devices of this generic type from class III to class II. Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21

U.S.C. 360c(f)(2)) and § 860.134 (21 CFR 860.134) provide for the reclassification by order of devices not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments.

Under section 513(f)(2) of the act and § 860.134, FDA may refer a reclassification petition to an appropriate panel. Although FDA did not refer the reclassification petitions submitted by the Acupuncture Coalition to a panel, the Anesthesiology Devices Advisory Panel (the Panel) had previously considered the classification of acupuncture needles and other acupuncture devices and recommended that acupuncture needles be placed into class II, as reported in the Federal Register of November 2, 1979 (44 FR 63292 at 63299) (Ref. 2). The supplemental data sheet completed by the Panel on November 30, 1976 (Ref. 3), listed sepsis, excessive trauma, and perforation of blood vessels and organs as specific risks, and recommended restricting the device to prescription use. FDA's decision to reclassify acupuncture needles as class II is in keeping with, but not dependent upon, the recommendation of the Panel.

FDA determined that acupuncture needles could safely be reclassified from class III to class II with the implementation of special controls. Acupuncture needles are devices intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle and may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

The order identified the special controls needed to provide reasonable assurance of the safety and effectiveness of acupuncture needles. Those special controls are in compliance with: (1) Labeling provisions for single use only and the prescription statement in § 801.109 (21 CFR 801.109) (restriction to use by or on the order of qualified practitioners as determined by the States), (2) device material biocompatibility, and (3) device sterility. FDA believes that information for use, including: Indications, effects, routes, methods, and frequency and duration of administration; and any hazards, contraindications, side effects, and precautions are commonly known to qualified practitioners of acupuncture. Therefore, under § 801.109(c), such indications do not need to be on the dispensing packaging, but sale must be clearly restricted to qualified practitioners of acupuncture as determined by the States. Guidance on the type of information needed to support biocompatibility and sterility of



acupuncture needles is available in the General Hospital Branch guidance document entitled "Guidance on the Content of Premarket Notification (510(k) Submissions for Hypodermic Single Lumen Needles" (draft), April 1993 (Ref. 4). A copy of this guidance document is available from the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850-4307, 301-443-6597 or 800-638-2041 and FAX 301-443-8818.

Consistent with the act and the regulations, after thorough review of the clinical data submitted in the petitions, and after FDA's own literature search, on March 29, 1996, FDA sent the Acupuncture Coalition a letter (order) reclassifying acupuncture needles for general acupuncture use, and substantially equivalent devices of this generic type, from class III to class II (special controls). As required by § 860.134(b)(7), FDA is announcing the reclassification of the generic type of device. Additionally, FDA is amending part 880 (21 CFR part 880) to include the classification of acupuncture needles for the practice of acupuncture by adding new § 880.5580.

#### Environmental Impact

The agency has determined that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Under 21 CFR 25.24(e)(2), the reclassification of a device is categorically exempt from environmental assessment and environmental impact statement requirements. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not

subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of devices from class III to class II will relieve some manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

#### Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this final rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (Pub. L. 104-13). Rather, the proposed warning statements are "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

#### References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA letter (order) to the Acupuncture Coalition dated March 29, 1996.
2. Classification of anesthesiology devices, development of general provisions; 44 FR 63292 at 63299, November 2, 1979.
3. Anesthesiology Devices Advisory Panel's supplemental data sheet, November 30, 1976.
4. Guidance on the Content of Premarket (510(k) Submissions for Hypodermic Single Lumen Needles (draft), April 1993.

#### List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

#### PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 880.5580 is added to subpart F to read as follows:

#### § 880.5580 Acupuncture needle.

(a) *Identification.* An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

(b) *Classification.* Class II (special controls). Acupuncture needles must comply with the following special controls:

- (1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,
- (2) Device material biocompatibility, and
- (3) Device sterility.

Dated: November 20, 1996.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96-31047 Filed 12-5-96; 8:45 am]

BILLING CODE 4160-01-F

#### DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

#### 24 CFR Part 5

[Docket No. FR-4154-C-02]

RIN 2501-AC36

#### Revised Restrictions on Assistance to Noncitizens; Correction

AGENCY: Office of the Secretary, HUD.

ACTION: Interim rule, correction.

**SUMMARY:** On November 29, 1996 (61 FR 60535), HUD published an interim rule implementing the changes made to Section 214 of the Housing and Community Development Act of 1980 by the Use of Assisted Housing by Aliens Act of 1996. Section 214 prohibits HUD from making certain financial assistance available to persons other than United States citizens, nationals, or certain categories of eligible noncitizens. The November 29, 1996 interim rule incorrectly provided for a public comment due date of November 29, 1996. The public comment due date should have been January 28, 1997, 60 days after publication of the November 29, 1996 interim rule. The purpose of this document is to correct the due date for public comments in the November 29, 1996 rule.



# Dry Needling is an Invasive Procedure H-410.949

<b>Topic: Practice Parameters</b>	<b>Policy Subtopic: NA</b>
Meeting Type: Annual	Year Last Modified: 2016
Action: NA	Type: Health Policies
Council & Committees: NA	undefined

Our AMA recognizes dry needling as an invasive procedure and maintains that dry needling should only be performed by practitioners with standard training and familiarity with routine use of needles in their practice, such as licensed medical physicians and licensed acupuncturists.

## Policy Timeline

Res. 223, A-16

## AAPM&R Position on Dry Needling

Dry needling is the use of solid needles (contrasted with the use of hollow hypodermic needles that are used for injections) to treat muscle pain by stimulating and breaking muscular knots and bands. Unlike trigger point injections used for the same purpose, no anesthetics are used. There is controversy regarding the definition of dry needling. Licensed medical physicians and licensed acupuncturists consider dry needling as *Western Style Acupuncture or Trigger Point Acupuncture* whereby the insertion sites are determined by tender painful areas and tight muscles. These sites may be treated alone or in combination with known acupuncture points. Other practitioners take the position that dry needling is different from acupuncture in that it is not a holistic procedure and does not use meridians or other Eastern medicine paradigms to determine the insertion sites. However, dry needling is taught in American acupuncture schools as a form of treatment for individuals using acupuncture needles.

Dry needling is an invasive procedure. Needle length can range up to 4 inches in order to reach the affected muscles. The patient can develop painful bruises after the procedure and adverse sequelae may include hematoma, pneumothorax, nerve injury, vascular injury and infection. Post procedure analgesic medications may be necessary (usually over the counter medications are sufficient).

There has been controversy in the United States as to who is qualified to practice dry needling. Since it is an invasive procedure using needles, many take the position that it should only be performed by licensed acupuncturists or licensed medical physicians (M.D. or D.O.). There are other practitioners performing this procedure who have taken a course or courses in this technique but do not routinely use needles otherwise in their practices.

The American Academy of Physical Medicine and Rehabilitation recognizes dry needling as an invasive procedure using acupuncture needles that has associated medical risks. Therefore, the AAPMR maintains that this procedure should only be performed by practitioners with standard training and familiarity with routine use of needles in their practice, such as licensed acupuncturists or licensed medical physicians.

June 2012

**aaPM&R**  
American Academy of  
Physical Medicine and Rehabilitation

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**AAMA Policy on Dry-Needling**

The American Academy of Medical Acupuncture (AAMA) is the premier North American organization of physician acupuncturists. The AAMA is committed to insuring public health and safety by ensuring that all persons practicing any type of medicine, including acupuncture, are properly trained and educated. It is imperative that courts and medical bodies maintain and preserve strict standards of education and training in acupuncture before any person undertakes inserting a needle into a patient. An ill-trained practitioner could, as a result of lack of education or ignorance, cause substantial medical injury.

Acupuncture, like Western Medicine is a complex subject. It cannot be mastered in a weekend or in a month. All AAMA members, in addition to four (4) years of medical school (MD or DO), must have 300 hours of didactic and clinical acupuncture education and training. In most states, a non-physician must have in excess of 2,000 hours of clinical and didactic education and training before they can become certified to treat patients.

Dry needling, like acupuncture, involves the use of solid needles (contrasted with the use of hollow hypodermic needles that are used for injections) to treat muscle pain by stimulating and breaking muscular knots and bands. Unlike trigger point injections used by physicians and licensed acupuncturists for the same purpose, no anesthetics are used in dry needling. There is controversy regarding the definition of dry needling. Licensed medical physicians and licensed acupuncturists consider dry needling as Western Style Acupuncture or Trigger Point Acupuncture whereby the insertion sites are determined by tender painful areas and tight muscles. These sites may be treated alone or in combination with known acupuncture points. Other practitioners take the position that dry needling is different from acupuncture in that it is not an holistic procedure and does not use meridians or other Eastern medicine paradigms to determine the insertion sites. Regardless of the theory, it is incontrovertible that dry needling is an invasive procedure. Needle length can range up to 4 inches in order to reach the affected muscles. It is critical to understand that dry needling, in the hands of minimally educated practitioners can cause extreme harm. Any invasive procedure has associated and potentially serious medical risks and is safe only if



performed by a properly educated, trained and experienced health professional. The technique of dry needling frequently involves needling of muscular structures that may be deep and/or hidden under layers of other muscles and tissues and close to sensitive structures and organs including blood vessels, nerves and organs as, for example, the lungs. The patient can develop painful bruises after the procedure and adverse sequelae may include hematoma, pneumothorax, nerve injury, vascular injury and infection. Angle the needle incorrectly and, for example, the lung may be punctured. Post procedure analgesic medications may be necessary (usually over the counter medications are sufficient). In the worse case scenario, vital organs can be pierced, resulting in complex medical situations or even death.

Physical therapy is not a field that has historically included the use of needles. The recent trend of some physical therapists to embrace dry needling under the umbrella of physical therapy practice is one that marks a distinct departure from traditional physical therapy practice. The fact that many physical therapists receive only minimal hours of training speaks to the potential danger of their practice.

To include dry needling into the scope of practice by physical therapists is unnecessarily to expose the public to serious and potentially hazardous risks. Because of this we feel a duty to inform legislators and regulating bodies about the inherent danger to the public of this practice.

Therefore, the AAMA strongly believes that, for the health and safety of the public, this procedure should be performed only by practitioners with extensive training and familiarity with routine use of needles in their practice and who are duly licensed to perform these procedures, such as licensed medical physicians or licensed acupuncturists. In our experience and medical opinion, it is inadvisable legally to expand the scope of physical therapists to include dry needling as part of their practice.

performed by a properly educated, trained and experienced health professional. The technique of dry needling frequently involves needling of muscular structures that may be deep and/or distant from the site of other muscles and tissues and often to a different structure and/or site. Dry needling involves needling nerves and organs as, for example, the lungs. The patient can develop a blood clot after the procedure and adverse reactions may include neurological, hematological, and respiratory. A needle injury and infection. A dry needling procedure may be necessary for the treatment of certain conditions. In the worst case scenario, vital organs can be pierced, resulting in a complex medical situation or even death.

Physical therapy is not a field that has historically included the use of needles. The use of needles in some physical therapy practices to enhance dry needling is the purview of physical therapy practices that have a distinct departure from traditional physical therapy practice. The fact that many physical therapists receive only minimal training in the potential dangers of their practice

to include dry needling into the scope of practice by physical therapists is unnecessary. It exposes the public to serious and potentially hazardous risks. Because of the widespread use of information legislators and regulatory bodies about the inherent danger to the public of this practice.

Therefore, the AMA strongly believes that for the health and safety of the public, this procedure should be performed only by practitioners with extensive training and familiarity with routine use of needles in their practice and who are duly licensed to perform this procedure. Such as licensed medical physicians or licensed acupuncturists. In our experience and medical opinion, it is inadvisable legally to expand the scope of any health caregiver to include dry needling as part of their practice.

**Title: Dry Needling**

Date Issued: March 21, 2014

Purpose: Clarify the dry-needling education requirement in Board Rule 211.D.2

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If the required course of at least 46 hours of in-person dry needling training is broken up into more than one part, then a licensed physical therapist is permitted the limited practice of dry needling once he or she has completed each part of the training as long as such practice is confined to the scope of the training already successfully completed, and with the understanding that all parts of the coursework will be successfully completed within 2 years of the start date of the course.

If the licensee has not completed at least 46 hours of in-person dry needling training within 2 years, then he/she must stop performing dry-needling at any level until he/she has completed at least 46 hours.

Once the licensed physical therapist has completed a minimum of 46 hours of in-person training in dry needling, then he or she may practice dry needling fully and without limitation as allowed in a physical therapist's scope of practice and commensurate with his or her knowledge, skill, ability, and competency.





Acupuncture Points and Meridians labelled for Dry Needling Class Instructions.



Another Dry Needling Class Labelling Acupuncture Points



Acupuncture Points labelled in dry needling class for the treatment of knee pain



Acupuncture Points used in the dry needling treatment of back pain



Another Dry Needling Class Labelled  
Acupuncture Points



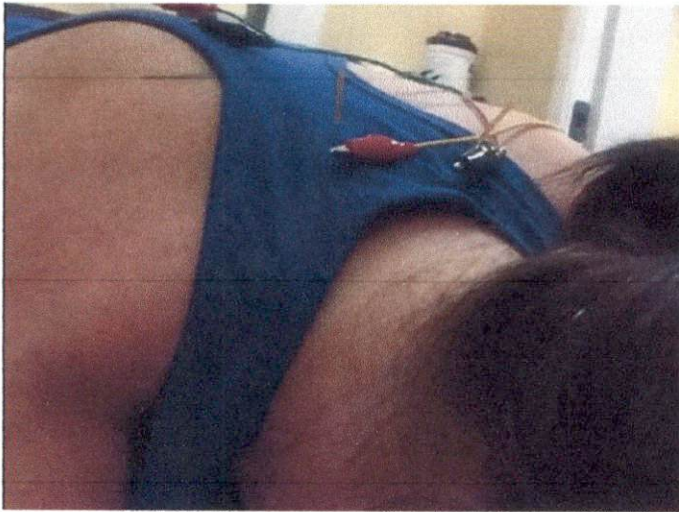
Acupuncture Points and Meridians Labelled for Dry  
Needling Class Instructional



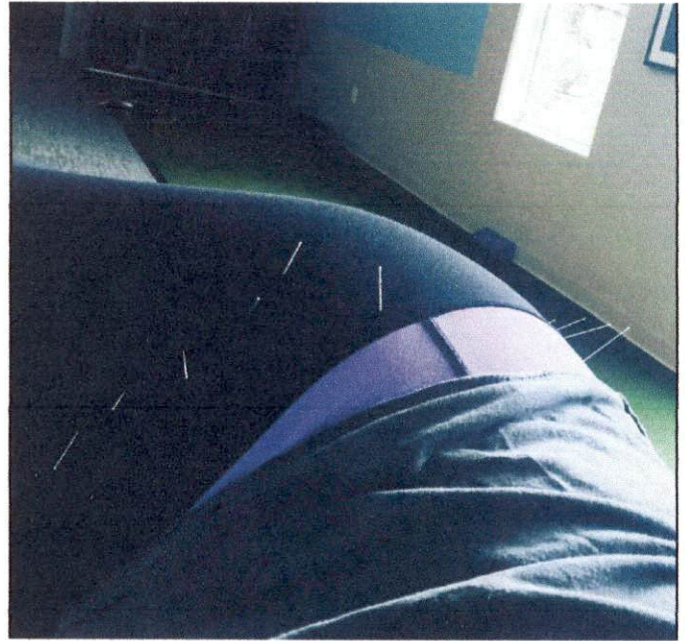
Acupuncture Point used in the Dry Needling  
treatment of back pain



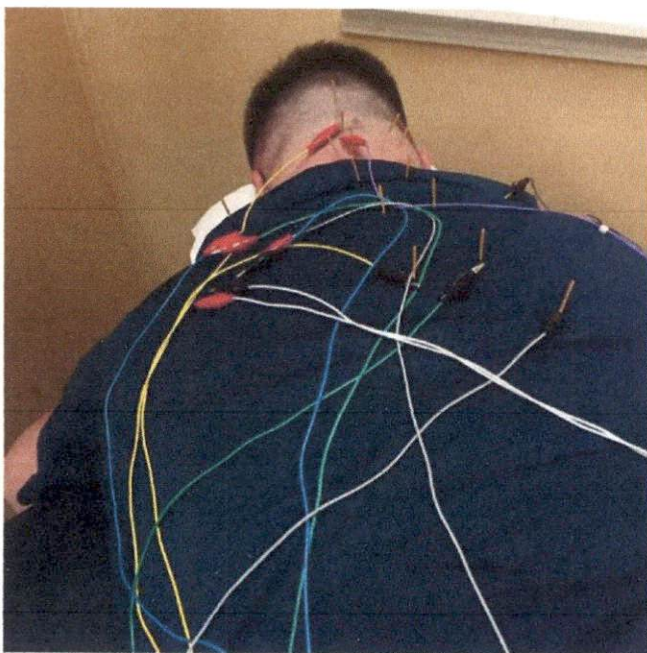
Acupuncture Point labelled in dry needling  
class for the treatment of knee pain



Dry Needling through clothes is a violation of Clean Needle Technique. Also, Electro-Stim on acupuncture needles demonstrated



Another example of dry needling through clothes



Dry Needling through clothes with electro-acupuncture



Distal point being used in Dry Needling for the treatment of headaches



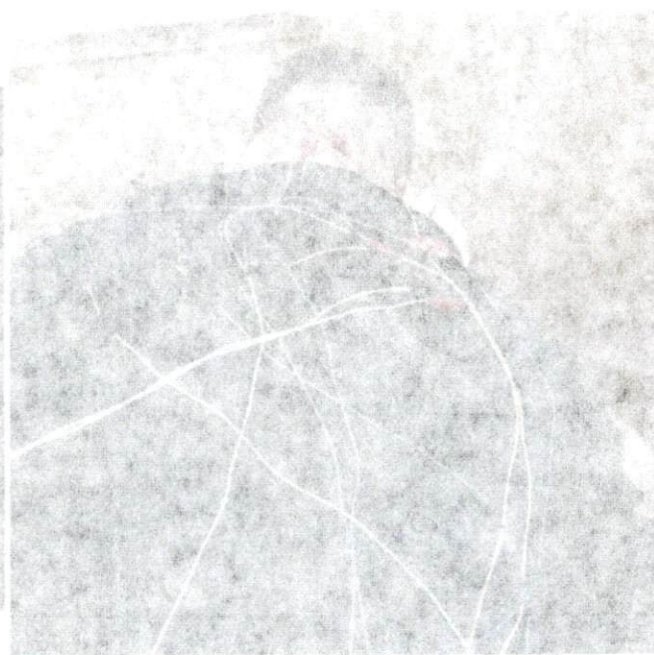
Another example of dry needles through clothes




Dry Needling through clothes is a violation of Clean Needle Technique. Wood blocks shown on acupuncture needles are illustrated



Digital point being used in Dry Needling for the treatment of back pain



Dry Needling through clothes with electric acupuncture



**SANDY BERTRAND**  
PHYSICAL THERAPY

HOME | SERVICES | LOCATIONS | BILLING & PAYMENT | TESTIMON

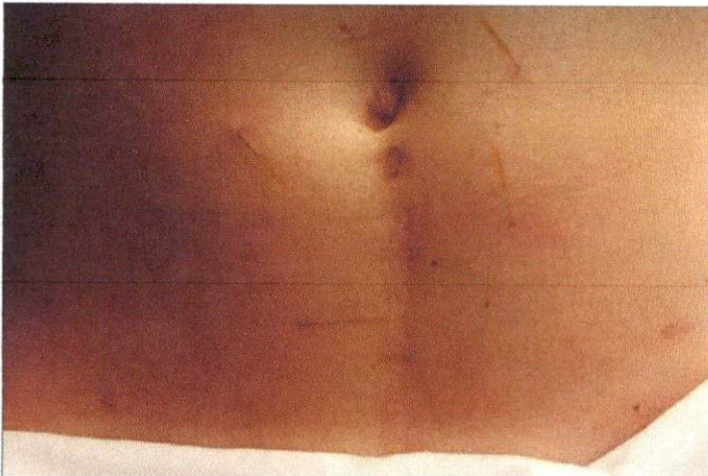
**SERVICES: INTEGRATIVE BIOMEDICAL NEEDLING**

"Integrative biomedical needling" is a philosophy developed by Dr. Yun Tao Ma, an internationally recognized acupuncturist and neuroscientist. It is a Dry needling philosophy which combines Trigger Point Dry Needling, Intermuscular Stimulation and Acupuncture points. With this approach we strive to have a physiological impact on the spinal cord segments which relate to the area of injury or pain, the local neuromuscular system and its relationship to trigger points as well as the whole system's homeostasis through the use of 24 common acupuncture points. This philosophy has been extremely successful in assisting in the recovery of acute, chronic, and overuse injuries. It helps to reduce pain and tension, promote healing, and reduce biomechanical and postural stress.

Services: **Manual Therapy | Movement Re-Training | Needling**  
**Biomechanical Analysis | Bike Fitting | Orthotics | Laser Therapy**



Cosmetic Dry Needling in Vail



Dry Needling for sinus congestion and allergies.

♡ 💬 📌

**63 likes**

**the.vagina.whisperer** Dry needling. This woman had endometriosis and secondary constipation. I use needling in my practice to help decrease tissue restriction, increase blood circulation, release trigger points and improve scar mobility. I'm not an acupuncturist and don't claim to do acupuncture. The needle is a tool, just like my hands are, to work on muscles and tissues. And the results are pretty freaking amazing. #thevaginawhisperer

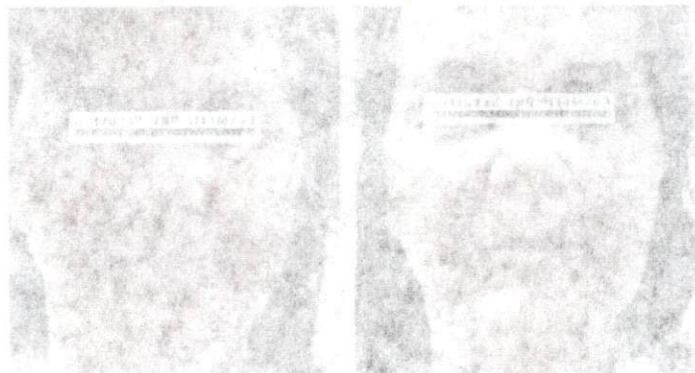


THE VAJINA WHISPER DRY NEEDLING

PROCESSES IN THE VAGINA DRY NEEDLING

As a physical therapist, I have seen many women with pelvic floor dysfunction. One of the most common symptoms is dry needling. This is a condition where the pelvic floor muscles are too tight and do not relax properly. This can lead to a variety of symptoms, including pain, urinary incontinence, and difficulty with sexual intercourse. Dry needling is a treatment that involves inserting thin needles into the muscle tissue to release tension and improve blood flow. This can help to relax the muscles and improve their function. In my practice, I use dry needling as a key component of my treatment plan for women with pelvic floor dysfunction. The results are often amazing, and the women feel a significant improvement in their symptoms. If you are experiencing any of these symptoms, I would encourage you to schedule a consultation with me to see if dry needling might be a helpful treatment for you.

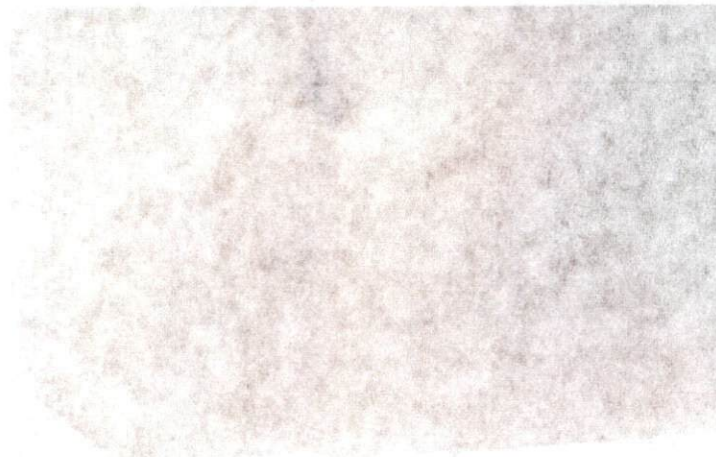
Services: Manual Therapy | Movement Re-education | Dry Needling  
Locations: Chicago, IL | Dallas, TX | Denver, CO



Cosmetic Dry Needling in Fall



Dry Needling for sinus congestion and allergies



63 likes

the vagina whisper dry needling. This is a condition where the pelvic floor muscles are too tight and do not relax properly. This can lead to a variety of symptoms, including pain, urinary incontinence, and difficulty with sexual intercourse. Dry needling is a treatment that involves inserting thin needles into the muscle tissue to release tension and improve blood flow. This can help to relax the muscles and improve their function. In my practice, I use dry needling as a key component of my treatment plan for women with pelvic floor dysfunction. The results are often amazing, and the women feel a significant improvement in their symptoms. If you are experiencing any of these symptoms, I would encourage you to schedule a consultation with me to see if dry needling might be a helpful treatment for you.