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Injection Workbook for **Adult Spasticity**

Examining Patient Assessment, Advanced Anatomy, and Injection Considerations

Indications

Adult Spasticity:

Adult Upper Limb Spasticity

BOTOX® for injection is indicated for the treatment of upper limb spasticity in adult patients to decrease the severity of increased muscle tone in elbow, wrist, finger, and thumb flexors (biceps, flexor carpi radialis, flexor carpi ulnaris, flexor digitorum profundus, flexor digitorum sublimis, adductor pollicis, and flexor pollicis longus).

Adult Lower Limb Spasticity

BOTOX® is indicated for the treatment of lower limb spasticity in adult patients to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).

Limitations of Use

Safety and effectiveness of BOTOX® have not been established for the treatment of other upper or lower limb muscle groups. BOTOX® has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening, and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat Cervical Dystonia and spasticity and at lower doses.

Please see additional Indication and Important Safety Information about BOTOX® inside.

Introduction

This workbook is designed to help hone your skills in identifying and evaluating Adult Spasticity patients who may be appropriate BOTOX[®] candidates, as well as implementing the BOTOX[®] Treatment Framework. We'll also discuss the resources and services offered by Allergan[®] as part of our commitment to support your practice.

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IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

BOTOX[®] is contraindicated in the presence of infection at the proposed injection site(s) and in patients who are hypersensitive to any botulinum toxin product or to any of the components in the formulation.

WARNINGS AND PRECAUTIONS

Spread of Toxin Effect

See Boxed Warning.

Lack of Interchangeability Between Botulinum Toxin Products

The potency Units of BOTOX[®] are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, Units of biological activity of BOTOX[®] cannot be compared to nor converted into Units of any other botulinum toxin products assessed with any other specific assay method.

Please see additional Important Safety Information about BOTOX[®] on following pages.

Integrate multiple approaches when assessing Adult Spasticity

Upper limb spasticity

Diagnosis Technique	Observations
Ask the patient what has impacted post-stroke treatment goals	“Muscle tightness” and “stiffness” are usually mentioned the most
Ask the patient if they have ever taken muscle relaxants	May indicate if another physician had noticed the spasticity
Have the patient stand up	Helps determine the effect of symptoms on balance and exposes the patient’s limbs
Shake the patient’s hand	Patient must extend 1 arm, allowing you to check for signs and symptoms in both limbs
Have patient raise their arms above their head and/or straight out	Allows you to quickly look for effects of spasticity on elbow, wrist, and fingers and/or straight out

Lower limb spasticity

Ambulatory Patients	Nonambulatory Patients*
Evaluate all affected joints of ankle and toe in all positions: supine, seated, standing, and moving	Look for potential skin breakdown caused by spasticity
Observe and evaluate patient’s gait, including gait cycle, as part of determining severity	Compare positioning when sitting vs lying down
Measure the time it takes for patient to walk a set distance or get up from seated position and walk to a set point	Determine if patient’s leg position impedes transfers

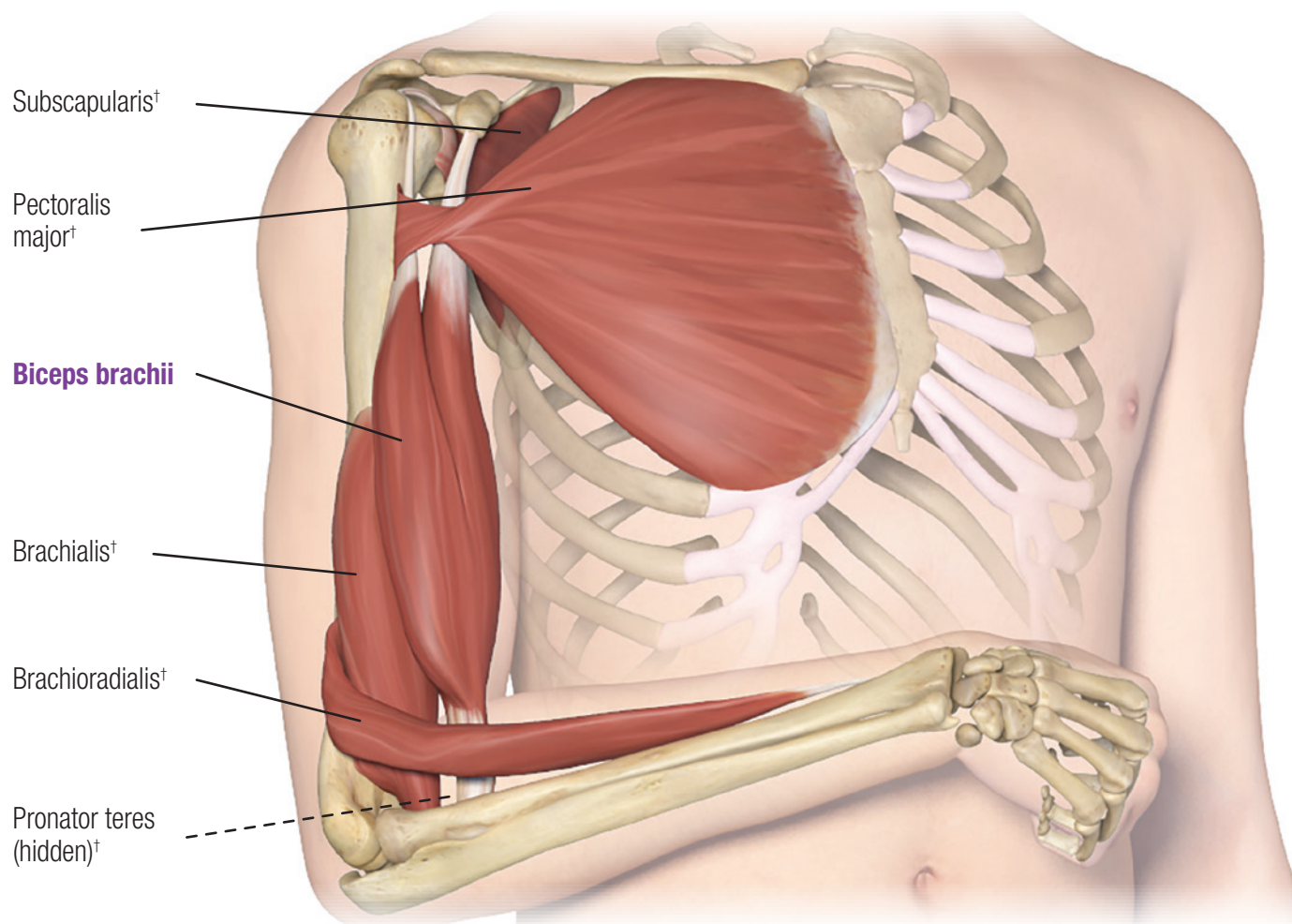
*Nonambulatory patients were excluded from the BOTOX[®] lower limb spasticity clinical trial.

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Clinical presentation in upper limb

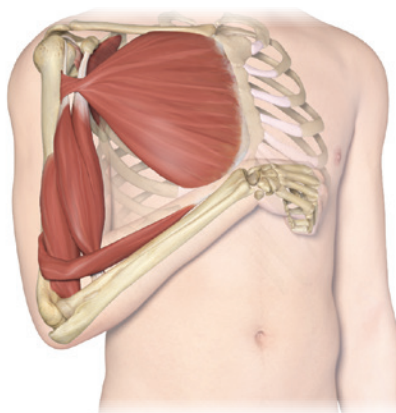
Upper limb posture combination*

Flexed elbow, pronated forearm, flexed wrist, flexed fingers, thumb in palm



*Wrist, finger, and thumb flexors (adductor pollicis, flexor carpi radialis, flexor carpi ulnaris, flexor digitorum profundus, flexor digitorum sublimis, flexor pollicis longus) are hidden as they are more readily identified in the anterior compartment of the forearm, which is not visible in this illustration.

[†]For anatomical reference only.



IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Increased Risk of Clinically Significant Effects With Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis (ALS), or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin.

Clinical presentation in upper limb (continued)

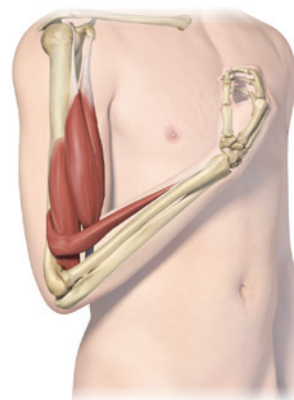
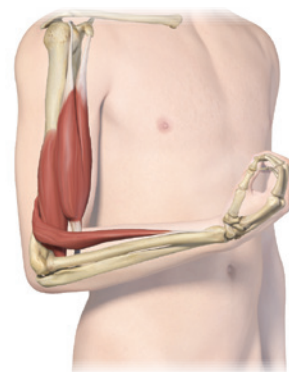
Flexed elbow, supinated forearm

**Biceps
brachii**

Brachialis*

Brachioradialis*

*For anatomical reference only.



IMPORTANT SAFETY INFORMATION (continued)

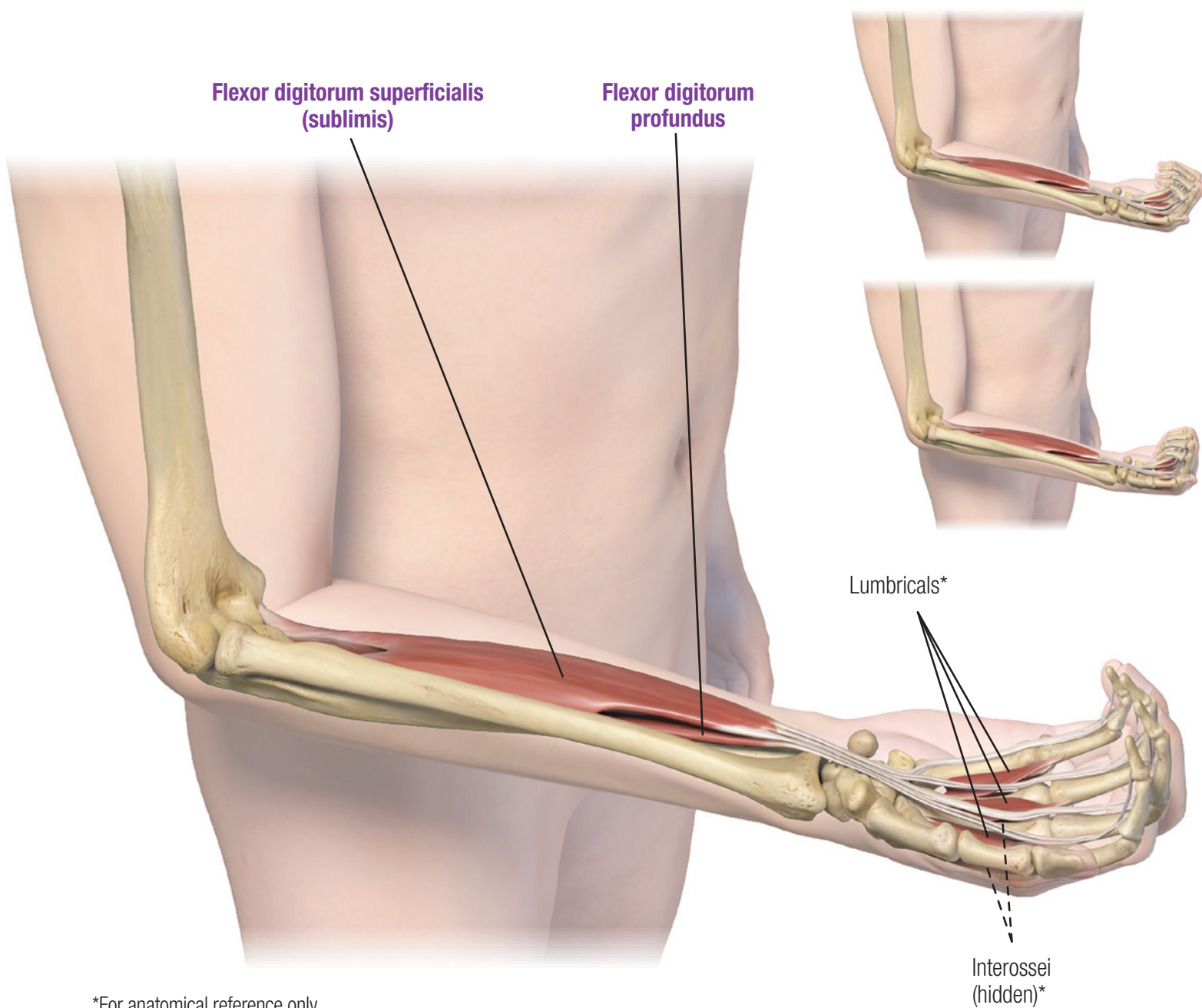
WARNINGS AND PRECAUTIONS (continued)

Dysphagia and Breathing Difficulties

Treatment with BOTOX[®] and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Clinical presentation in upper limb (continued)

Flexed fingers



*For anatomical reference only.

IMPORTANT SAFETY INFORMATION (continued)

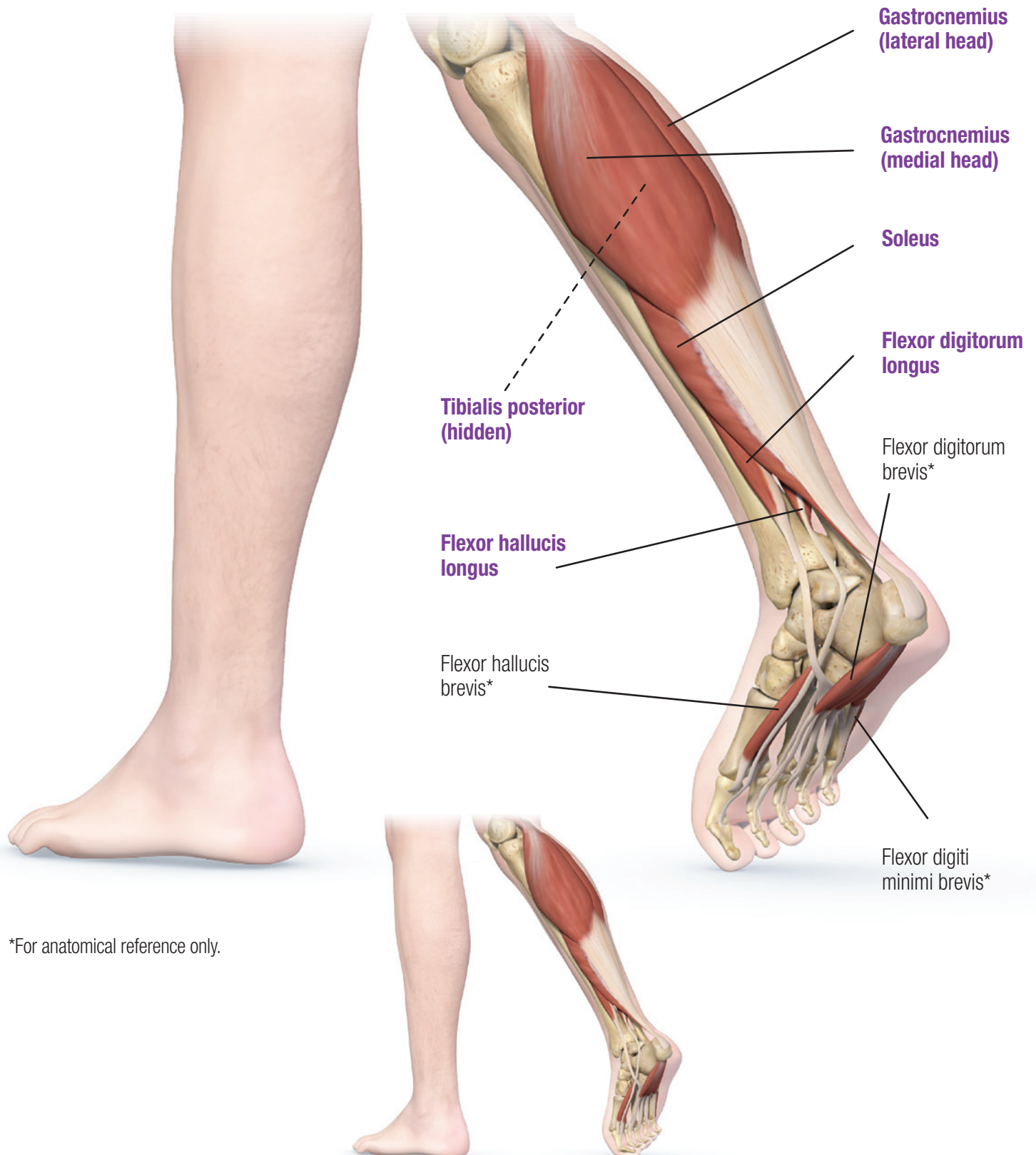
WARNINGS AND PRECAUTIONS (continued)

Bronchitis and Upper Respiratory Tract Infections in Patients Treated for Spasticity

Bronchitis was reported more frequently as an adverse reaction in adult patients treated for upper limb spasticity with BOTOX[®] (3% at 251 Units to 360 Units total dose) compared to placebo (1%). In adult patients with reduced lung function treated for upper limb spasticity, upper respiratory tract infections were also reported more frequently as adverse reactions in patients treated with BOTOX[®] (11% at 360 Units total dose; 8% at 240 Units total dose) compared to placebo (6%).

Clinical presentation in lower limb

Flexed ankle, flexed toes



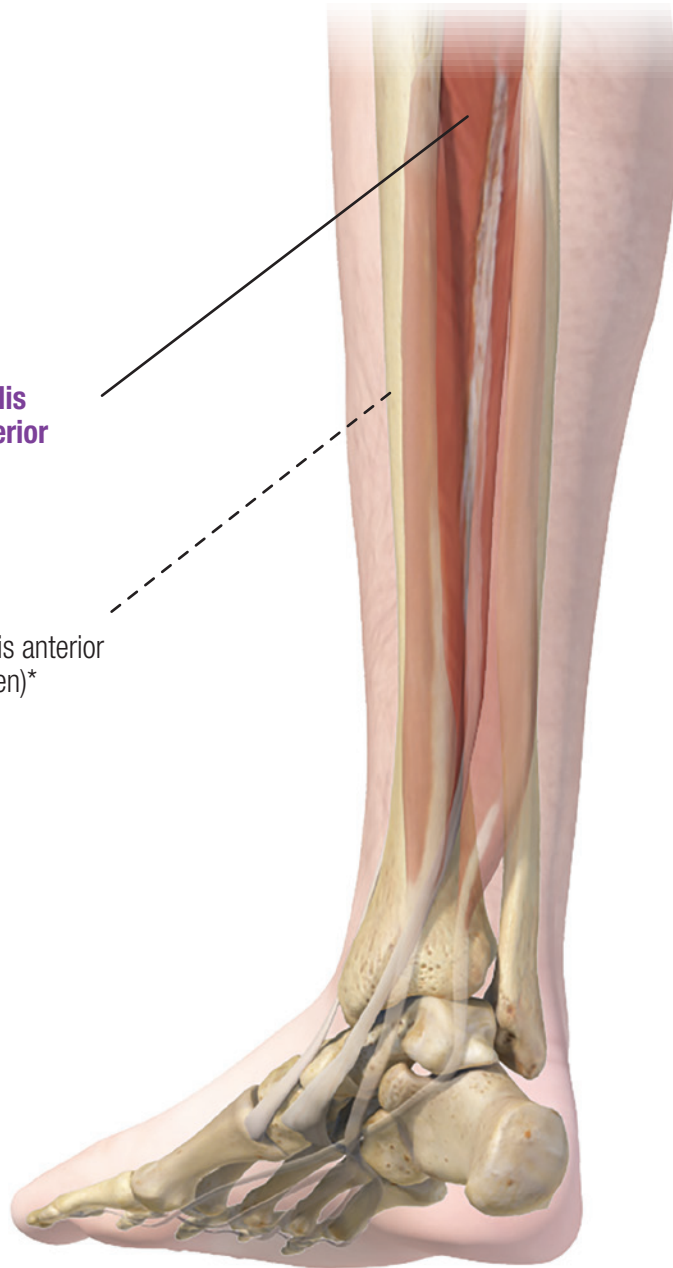
*For anatomical reference only.

Clinical presentation in lower limb (continued)

Inverted/supinated foot

Tibialis posterior

Tibialis anterior
(hidden)*



*For anatomical reference only.

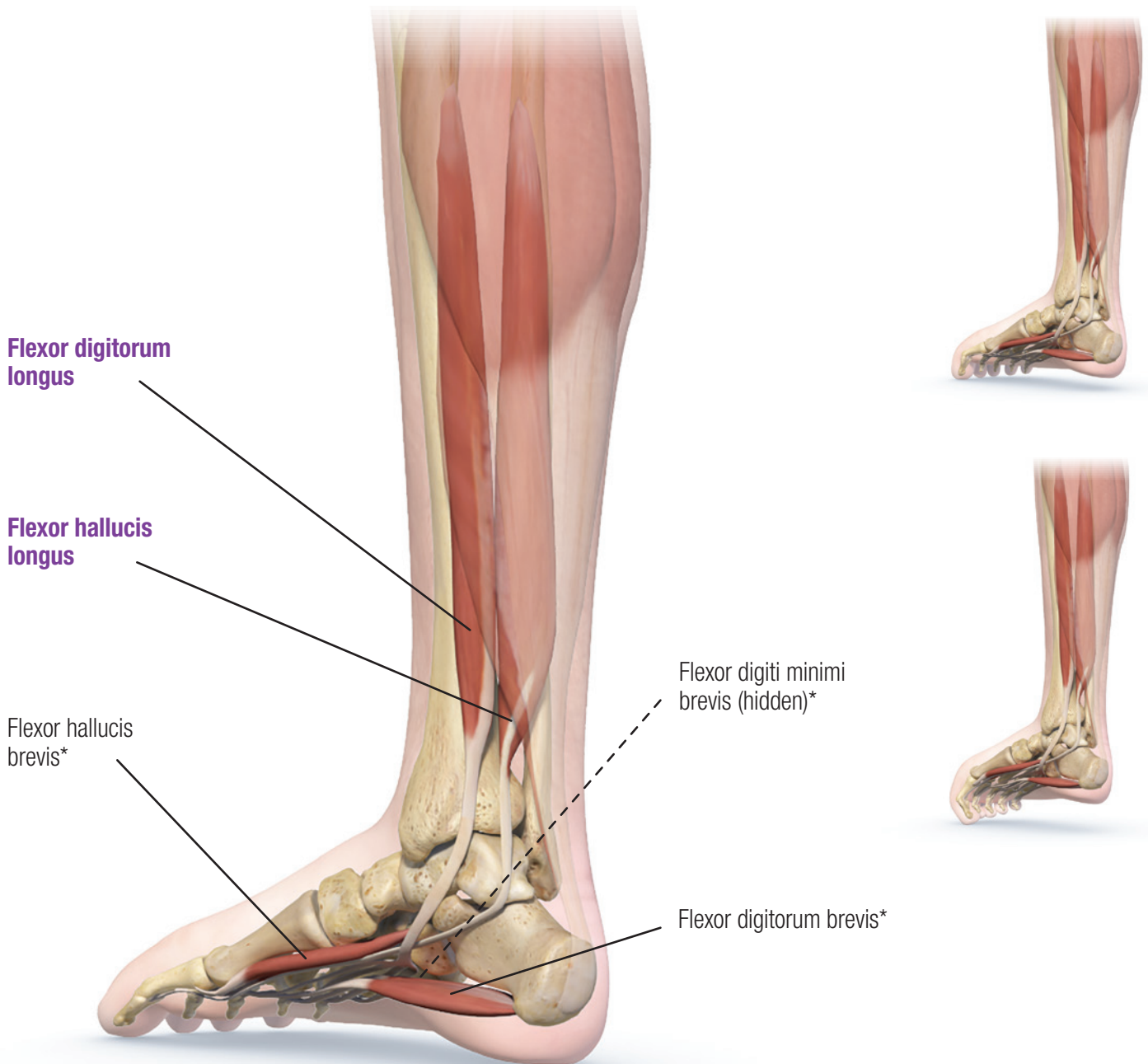
IMPORTANT SAFETY INFORMATION (continued) ADVERSE REACTIONS

Adverse reactions to BOTOX[®] for injection are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

Please see additional Important Safety Information about BOTOX[®] on following pages.

Clinical presentation in lower limb (continued)

Flexed toes



*For anatomical reference only.

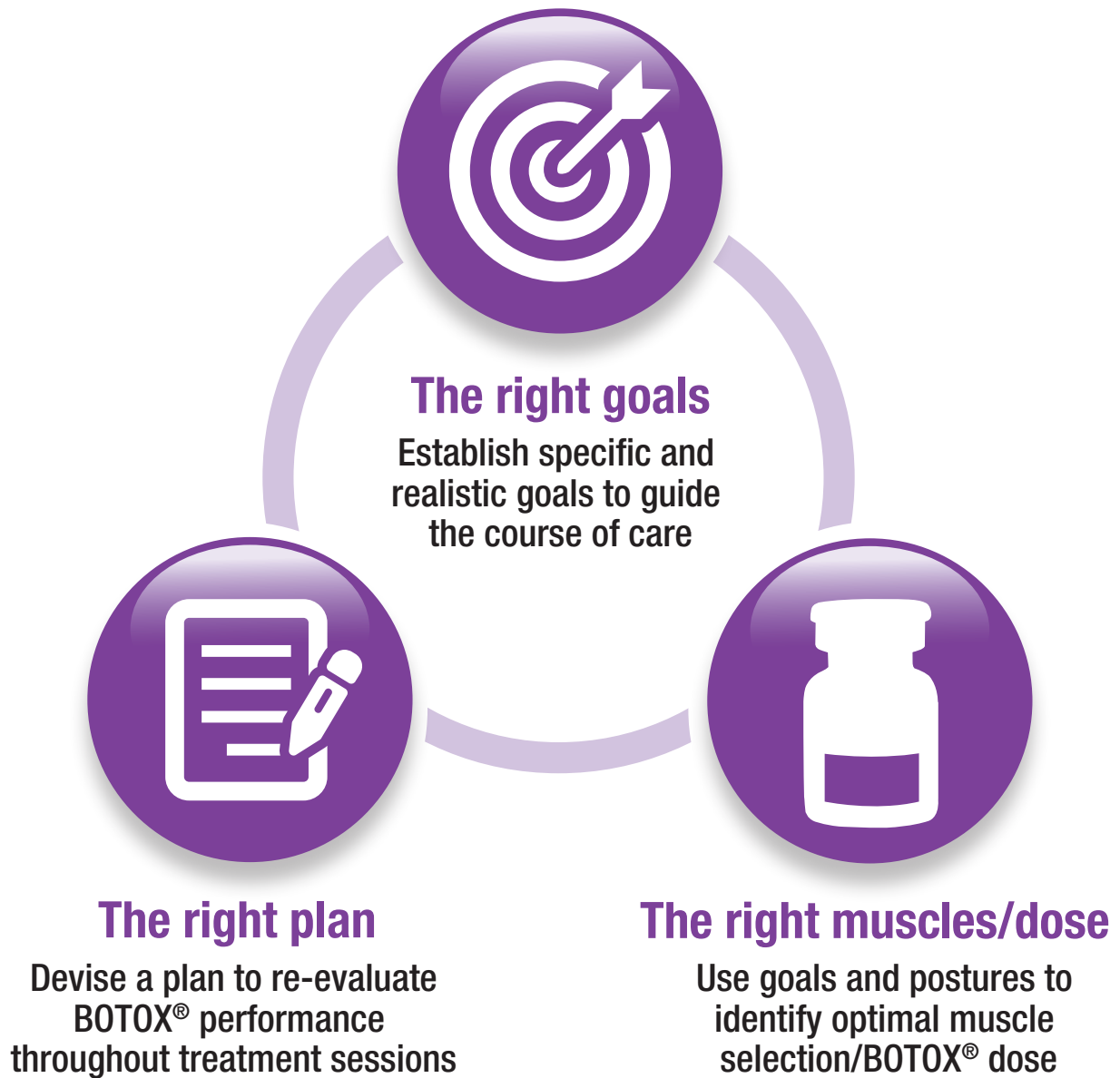
IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS (continued)

Adult Upper Limb Spasticity

The most frequently reported adverse reactions following injection of BOTOX[®] for upper limb spasticity include pain in extremity, muscular weakness, fatigue, nausea, and bronchitis.

Overview of the BOTOX[®] Treatment Framework



IMPORTANT SAFETY INFORMATION (continued)

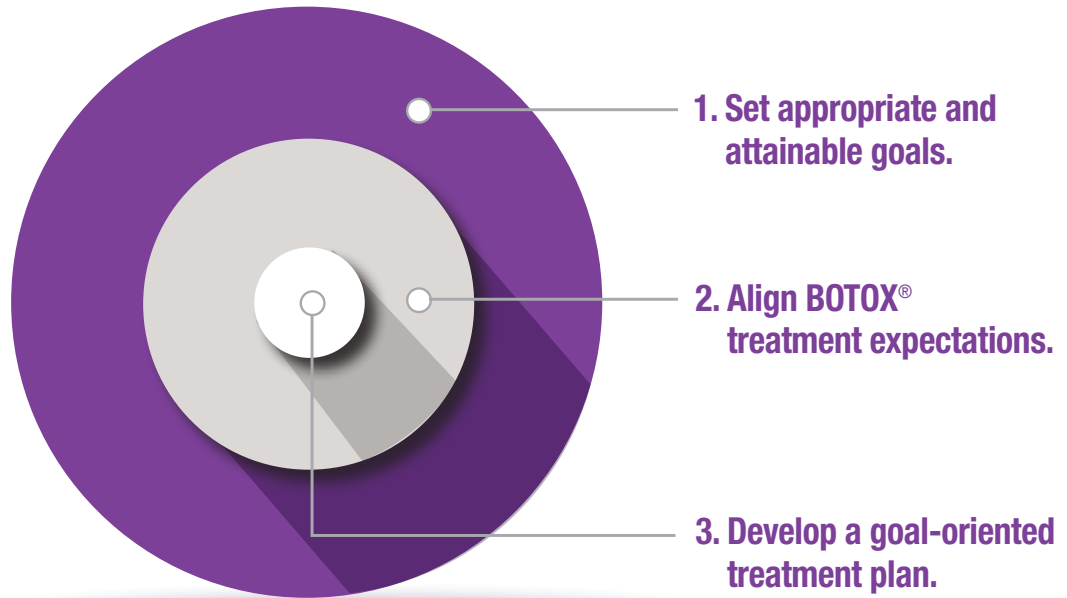
ADVERSE REACTIONS (continued)

Postmarketing Experience

Adverse reactions that have been identified during postapproval use of BOTOX[®] are discussed in greater detail in Postmarketing Experience (Section 6.3 of the Prescribing Information).

There have been spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility or anaphylaxis, after treatment with botulinum toxin. There have also been reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including cardiovascular disease. The exact relationship of these events to the botulinum toxin injection has not been established.

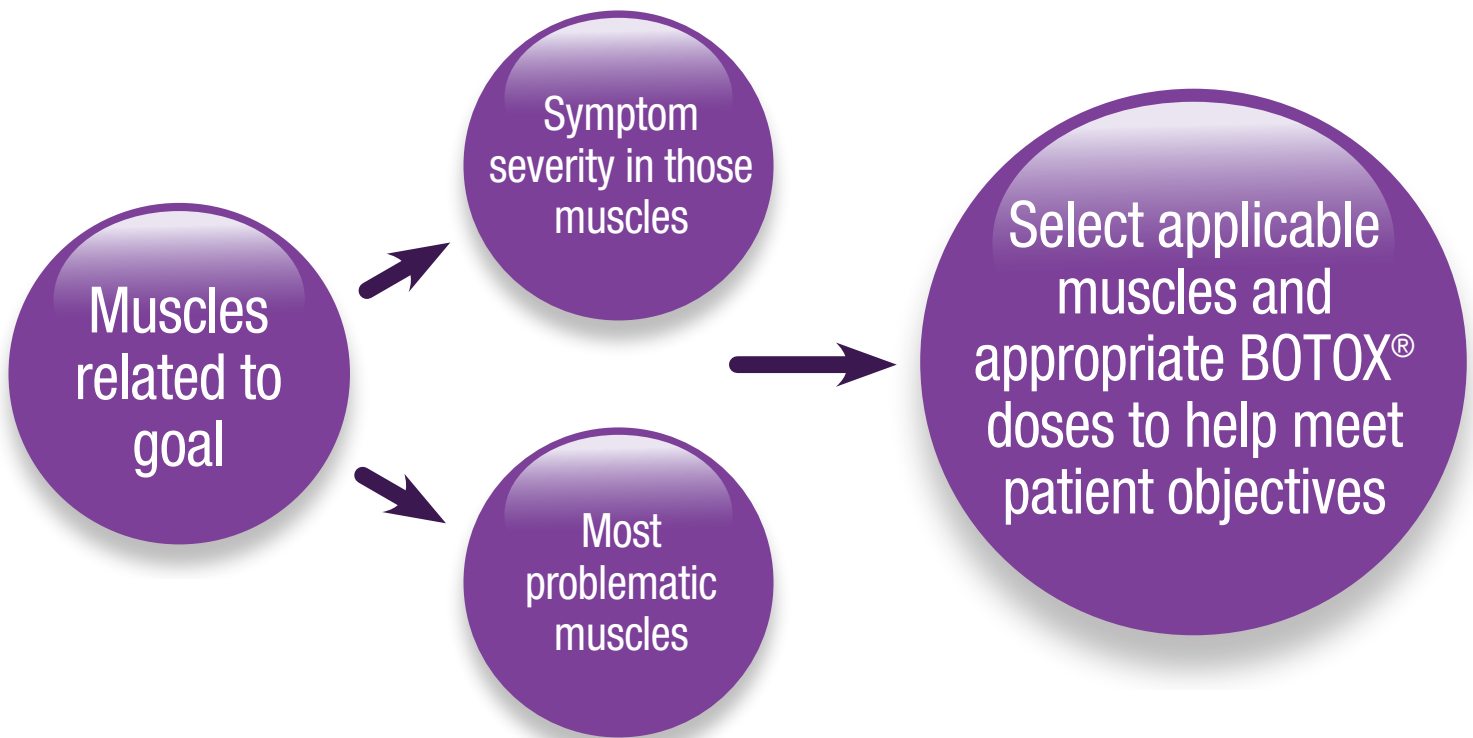
Take a strategic approach to treatment planning



Treatment-planning considerations

	Challenge ^{1,2}	Opportunity
Goal setting	Patients are often misaligned with their clinicians about treatment goals	Use a structured process to uncover and communicate individualized and realistic patient goals
Communication	Patients may respond negatively to words they find scary or too scientific	Consider avoiding phrases like “toxin,” “efficacy,” and “paralyze the muscle”
Cost/Patient perception	If treatment doesn’t meet expectations, patients may feel it’s “not worth” the out-of-pocket cost	Reinforce that it takes time and effort to see results, which may change their perception about BOTOX [®] treatment

Prioritize muscle/dose selection based on treatment goals



Adjust muscle/dose selections based on goal status and treatment response

IMPORTANT SAFETY INFORMATION (continued)

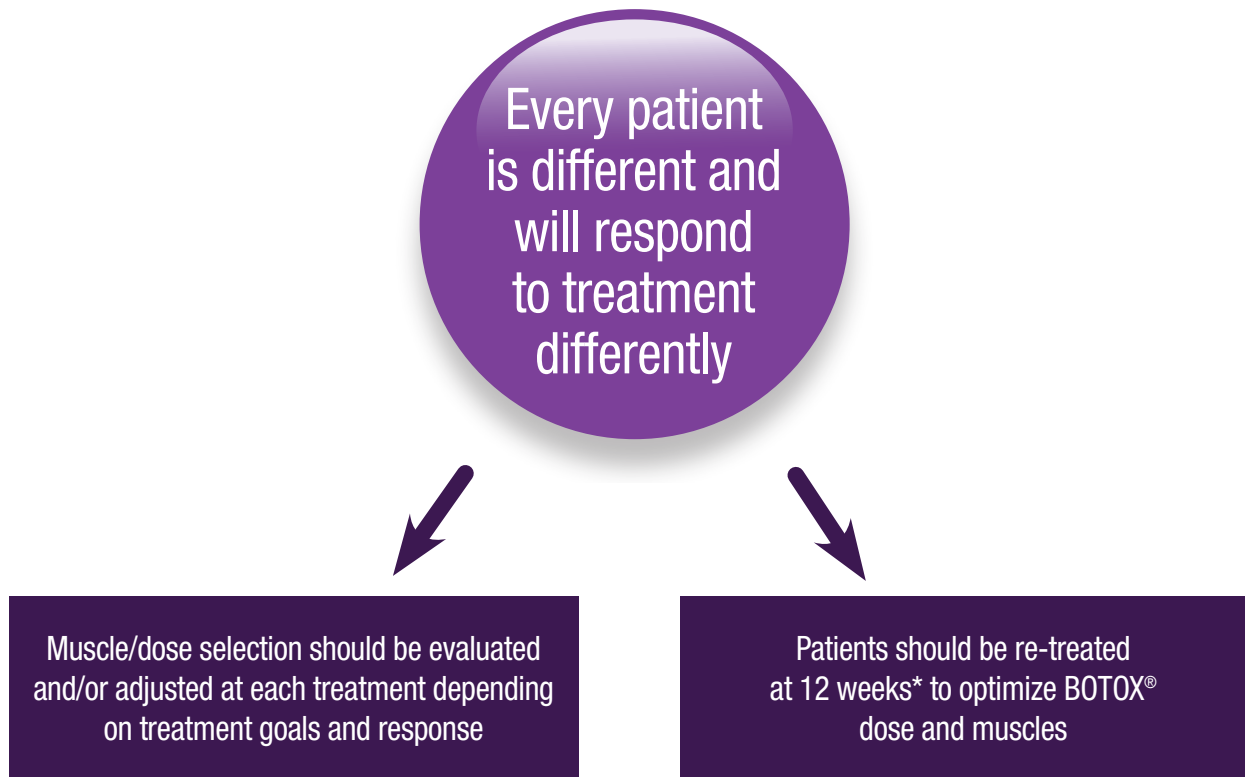
WARNINGS AND PRECAUTIONS (continued)

Serious Adverse Reactions With Unapproved Use

Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX[®] injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX[®] to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX[®]. The safety and effectiveness of BOTOX[®] for unapproved uses have not been established.

Please see additional Important Safety Information about BOTOX[®] on following pages.

Key principles to setting up an effective treatment plan



Treatment-planning considerations

	Challenge ^{1,2}	Opportunity
The role of BOTOX[®]	Patients should understand that BOTOX [®] is part of a larger treatment plan	Educate patients about the importance of adhering to PT/OT, orthoses, oral therapies, etc
Follow-up	Patients can benefit from learning that their BOTOX [®] treatment plan is an ongoing process and may evolve over time	Educate patients that at each follow-up and treatment appointment, you'll assess progress and make adjustments as needed
Reviewing progress	Patients may not have an established role in tracking their treatment progress	Encourage patients to use simple, quantifiable methods to track their progress and communicate it at every appointment

*Patients should be considered for reinjection when the clinical effect of the previous injection has diminished but no sooner than 12 weeks from the previous injection.

Muscles by posture in Adult Spasticity

Posture	Muscles	
	Upper limb spasticity ^{18,19}	
Pronated flexed elbow	<ul style="list-style-type: none"> • Biceps brachii • Brachialis* 	<ul style="list-style-type: none"> • Brachioradialis* • Pronator teres*
Supinated flexed elbow	<ul style="list-style-type: none"> • Biceps brachii • Brachialis* 	<ul style="list-style-type: none"> • Brachioradialis*
Flexed wrist	<ul style="list-style-type: none"> • Flexor carpi radialis • Flexor carpi ulnaris • Flexor digitorum profundus 	<ul style="list-style-type: none"> • Flexor digitorum superficialis (sublimis) • Flexor pollicis longus • Palmaris longus*
Flexed fingers	<ul style="list-style-type: none"> • Flexor digitorum profundus • Flexor digitorum superficialis (sublimis) 	<ul style="list-style-type: none"> • Interossei* • Lumbricals*
Thumb in palm	<ul style="list-style-type: none"> • Abductor pollicis brevis* • Adductor pollicis • Flexor pollicis brevis* 	<ul style="list-style-type: none"> • Flexor pollicis longus • Opponens pollicis*
	Lower limb spasticity ^{18,19}	
Flexed ankle	<ul style="list-style-type: none"> • Flexor digitorum longus • Flexor hallucis longus • Tibialis posterior 	<ul style="list-style-type: none"> • Gastrocnemius • Soleus
Flexed toes	<ul style="list-style-type: none"> • Flexor digitorum longus • Flexor digiti minimi brevis* • Flexor digitorum brevis* 	<ul style="list-style-type: none"> • Flexor hallucis longus • Flexor hallucis brevis*
Inverted/supinated foot	<ul style="list-style-type: none"> • Tibialis anterior* 	<ul style="list-style-type: none"> • Tibialis posterior

*For anatomical reference only.

Prioritize which muscles/dose to inject based on the established treatment goals

Injection insights and considerations (continued)

Before injection

- Examine the patient to identify the muscles contributing to the posture(s) and spasticity
 - Isolate the involved muscles using a clinical exam as well as guidance techniques
-
- Verify the needle is securely fastened to the injection syringe
-
- Consider the type of needle/syringe to minimize the chance of the needle popping out during the injection
-
- Consider using *Luer-Lok*[®] syringes to prevent the leakage of BOTOX[®] during the injection
-
- Consider lining up the bevel of the needle with the gradations on the syringe so the bevel is facing upward; this will help you read the syringe when injecting
-
- Consider discussing the option of using cold spray to numb the injection site(s) with your patients
-
- Explain that some injection sites may be more sensitive than others so the pain level can vary with each injection
-

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Dysphagia and Breathing Difficulties

Treatment with BOTOX[®] and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Pulmonary Effects of BOTOX[®] in Patients With Compromised Respiratory Status Treated for Spasticity

Patients with compromised respiratory status treated with BOTOX[®] for adult spasticity should be monitored closely.

Bronchitis and Upper Respiratory Tract Infections in Patients Treated for Spasticity

Bronchitis was reported more frequently as an adverse reaction in adult patients treated for upper limb spasticity with BOTOX[®] (3% at 251 Units to 360 Units total dose) compared to placebo (1%). In adult patients with reduced lung function treated for upper limb spasticity, upper respiratory tract infections were also reported more frequently as adverse reactions in patients treated with BOTOX[®] (11% at 360 Units total dose; 8% at 240 Units total dose) compared to placebo (6%). In adult patients treated for lower limb spasticity, upper respiratory tract infections were reported more frequently as an adverse reaction in patients treated with BOTOX[®] (2% at 300 Units to 400 Units total dose), compared to placebo (1%).

Main muscles involved in Adult Upper Limb Spasticity

Muscles listed in purple are those approved for BOTOX[®] injection¹⁸

Anterior view

Biceps Brachii

100 Units to 200 Units
divided in 4 sites

Brachioradialis*

Extensor Carpi
Radialis Longus*

Flexor Pollicis Longus

20 Units in 1 site

Adductor Pollicis

20 Units in 1 site

Brachialis*

Pronator Teres*

Flexor Carpi Radialis

12.5 Units to 50 Units in 1 site

Palmaris Longus*

Flexor Carpi Ulnaris

12.5 Units to 50 Units in 1 site

Flexor Digitorum Profundus (hidden)

30 Units to 50 Units in 1 site

Flexor Digitorum Superficialis (Sublimis)

30 Units to 50 Units in 1 site

*For anatomical reference only.
Lines indicate muscle location, and do
not point out sites for injection.

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

Adverse reactions to BOTOX[®] for injection are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

Please see additional Important Safety Information about BOTOX[®] on following pages.

Biceps brachii

► BOTOX[®] dose: 100 Units to 200 Units divided in 4 sites

Muscle action¹⁹

Supinates the forearm and flexes the elbow

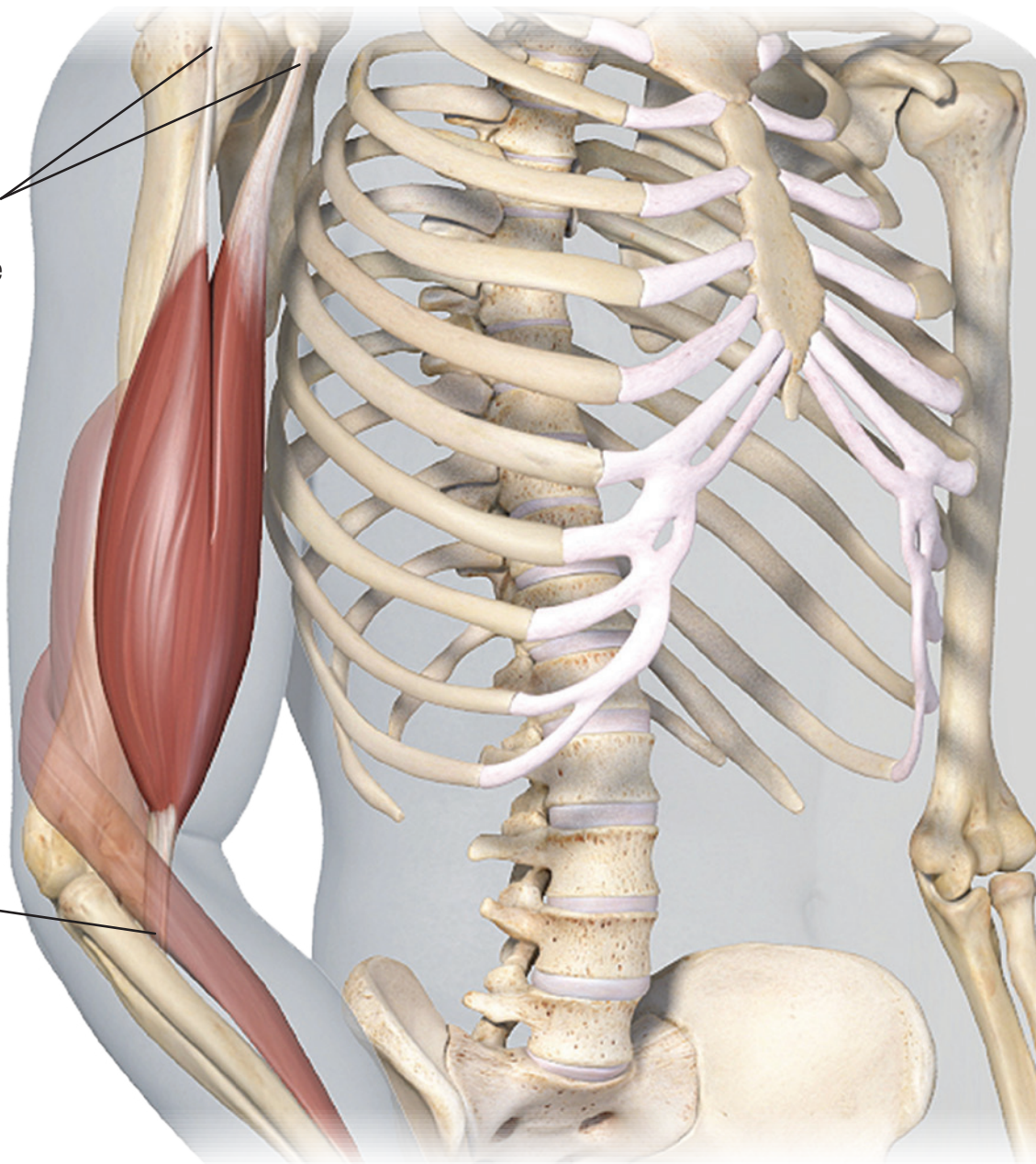
Proximal attachments

Long head arises from the supraglenoid tubercle of the scapula

Short head arises from the coracoid process

Distal attachment

Radial tuberosity



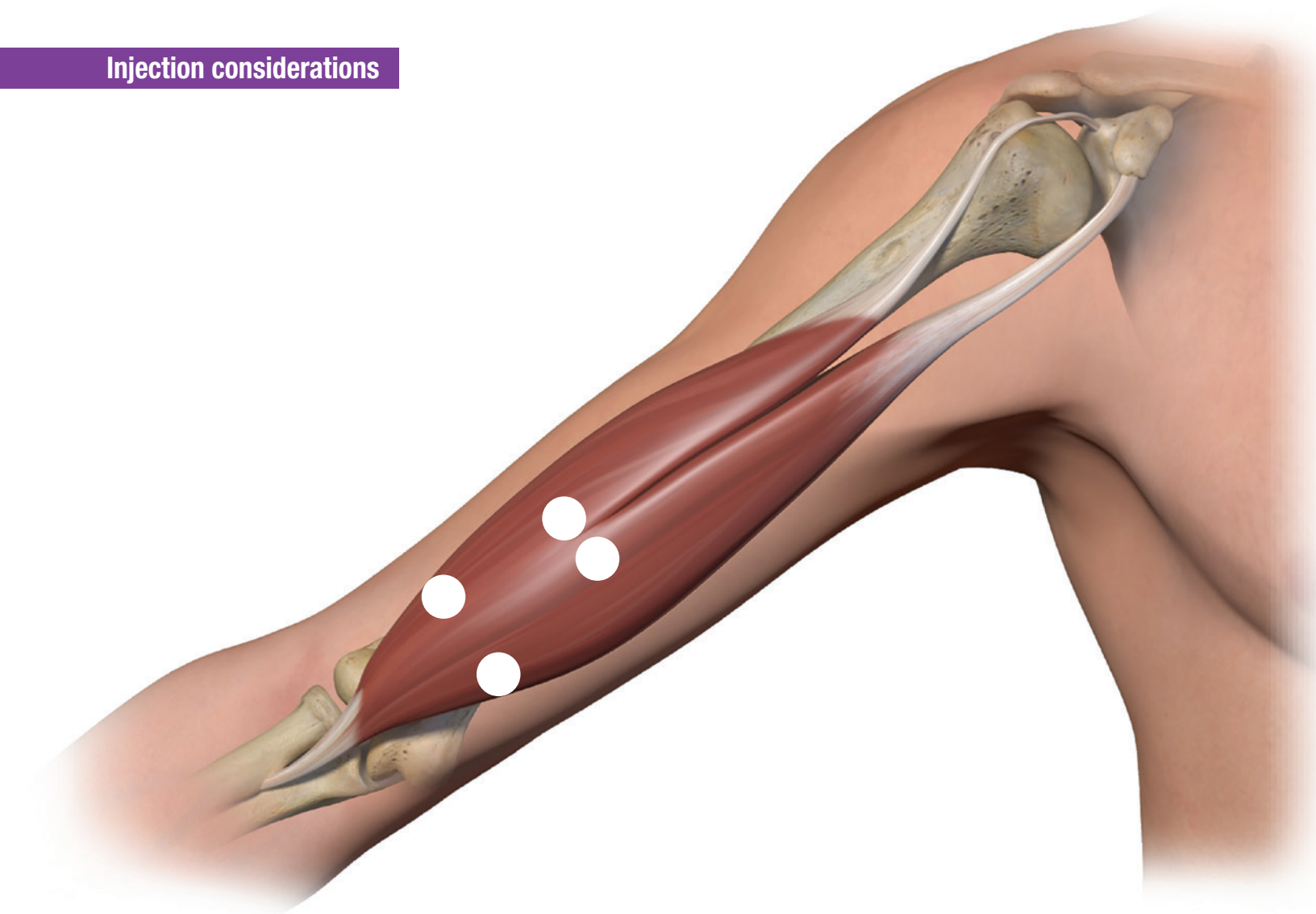
Other muscles involved in elbow flexion/forearm supination

- Brachialis (flexion only)*
- Supinator (supination only)*
- Brachioradialis (flexion only)*

*For anatomical reference only.

Biceps brachii (continued)

Injection considerations



- Extend the forearm, if possible, and approach the muscle through the anterior aspect of the biceps to avoid the vascular areas
- Consider using an inverted V pattern at the junction of the middle and lower third of the muscle when injecting the 4 sites
- Biceps muscles may be thinner in some individuals

IMPORTANT SAFETY INFORMATION (continued) **ADVERSE REACTIONS (continued)**

Adult Lower Limb Spasticity

The most frequently reported adverse reactions following injection of BOTOX[®] for lower limb spasticity include arthralgia, back pain, myalgia, upper respiratory tract infection, and injection-site pain.

Please see additional Important Safety Information about BOTOX[®] on following pages.

Flexor carpi radialis

► BOTOX[®] dose: 12.5 Units to 50 Units (1 site)

Muscle action¹⁹

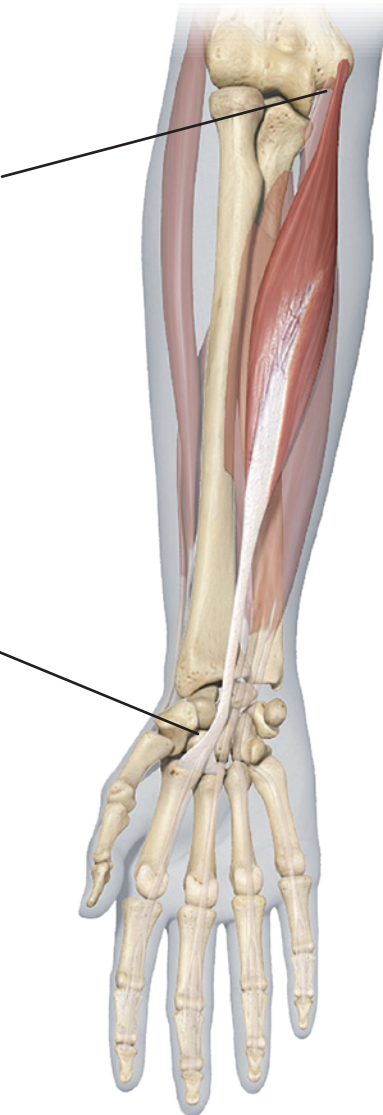
Flexes the wrist and also abducts (radially deviates) the hand

Proximal attachment

Medial epicondyle via the common flexor tendon

Distal attachment

Palmar surface of the base of the second metacarpal



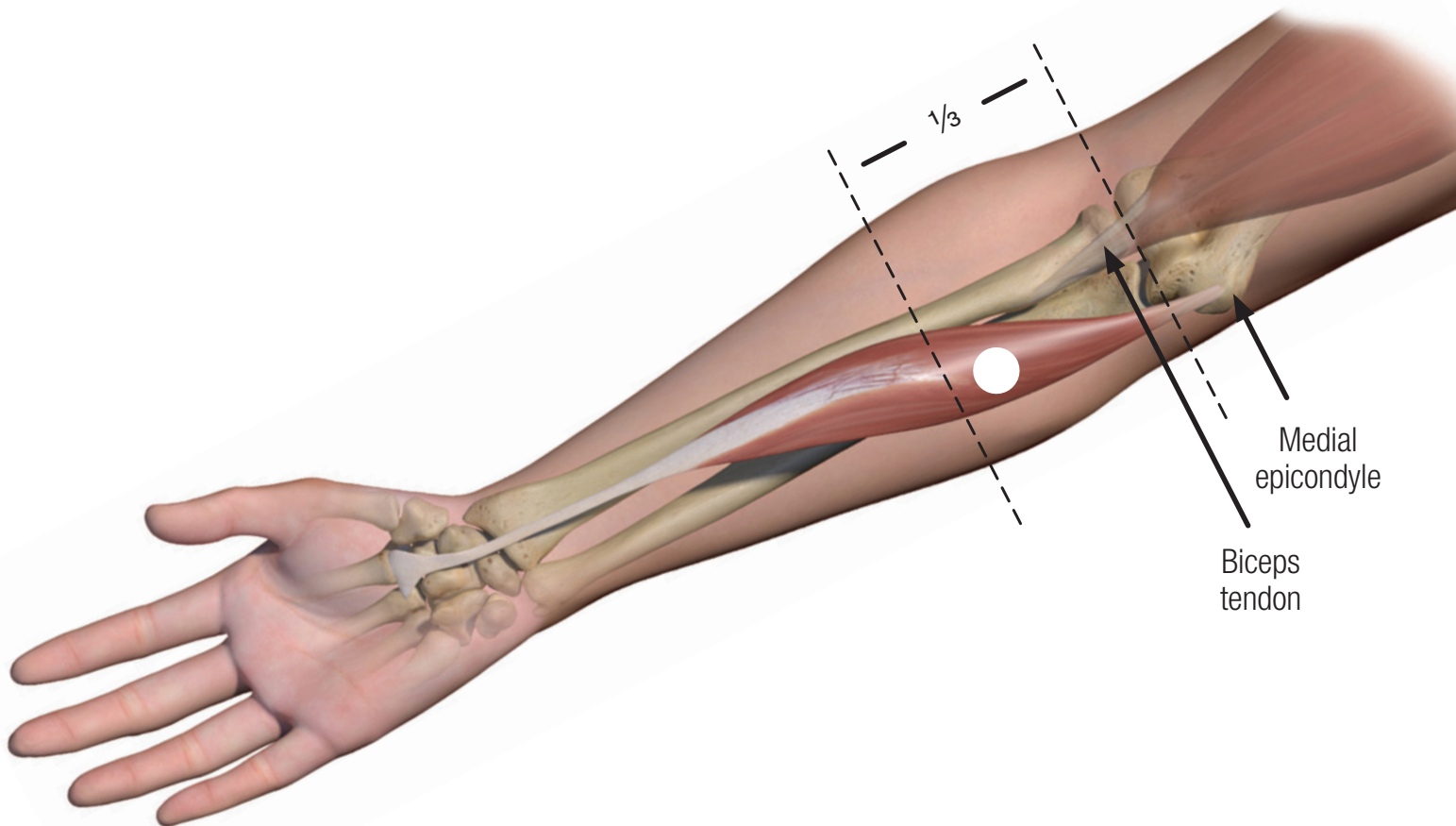
Other muscles involved in wrist flexion/abduction

- Flexor carpi ulnaris (flexion only)
- Flexor digitorum superficialis (flexion only)
- Flexor digitorum profundus (flexion only)
- Flexor pollicis longus (flexion only)
- Palmaris longus (flexion only)*
- Extensor carpi radialis longus (abduction only)*
- Abductor pollicis longus (abduction only)*
- Extensor pollicis longus (abduction only)^{21,*}

*For anatomical reference only.

Flexor carpi radialis (continued)

Injection considerations



- If possible, place the forearm in a neutral position, put 1 finger on the bicep tendon and 1 finger on the medial epicondyle, bisect the line, and palpate the muscle with passive flexion
- Consider injecting in the proximal 1/3 of the forearm, in the largest part of the muscle
 - If you are in the mid forearm, you may be in the wrong muscle
- Avoid going too deep to avoid inadvertent injection of neighboring muscles

IMPORTANT SAFETY INFORMATION (continued)

DRUG INTERACTIONS

Co-administration of BOTOX[®] and other agents interfering with neuromuscular transmission (eg, aminoglycosides, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX[®] may potentiate systemic anticholinergic effects. The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX[®].

Please see the accompanying BOTOX[®] full Prescribing Information including Boxed Warning and Medication Guide.

Flexor carpi ulnaris

► BOTOX[®] dose: 12.5 Units to 50 Units (1 site)

Muscle action¹⁹

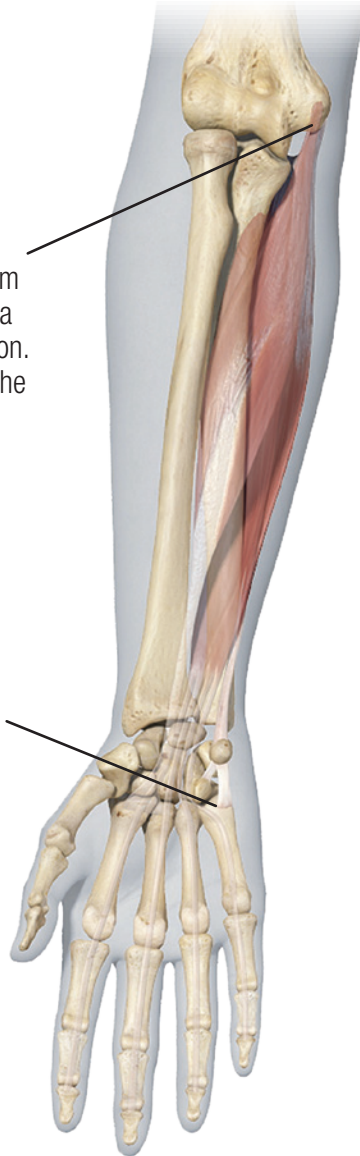
Flexes the wrist and also adducts (ulnarly deviates) the hand

Proximal attachment

Humeral head arises from the medial epicondyle via the common flexor tendon. Ulnar head arises from the olecranon and proximal two-thirds of the ulna

Distal attachment

To the pisiform and further to the hamate and fifth metacarpal by pisohamate and pisometacarpal ligaments



Other muscles involved in wrist flexion/adduction

- Flexor carpi radialis (flexion only)
- Flexor digitorum profundus (flexion only)
- Flexor digitorum superficialis (flexion only)
- Flexor pollicis longus (flexion only)
- Palmaris longus (flexion only)*
- Extensor carpi ulnaris (adduction only)*

*For anatomical reference only.

Flexor carpi ulnaris (continued)

Injection considerations



- If possible, position the limb in a comfortable position and localize using 2 fingerbreadths volar to the ulna
- Consider targeting the injection site in the ulnar portion of the volar forearm
- This muscle is very thin and superficial, so be aware of the surrounding nerves, arteries, and veins that are in the trajectory of the needle path

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Serious Adverse Reactions With Unapproved Use

Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX[®] injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX[®] to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX[®]. The safety and effectiveness of BOTOX[®] for unapproved uses have not been established.

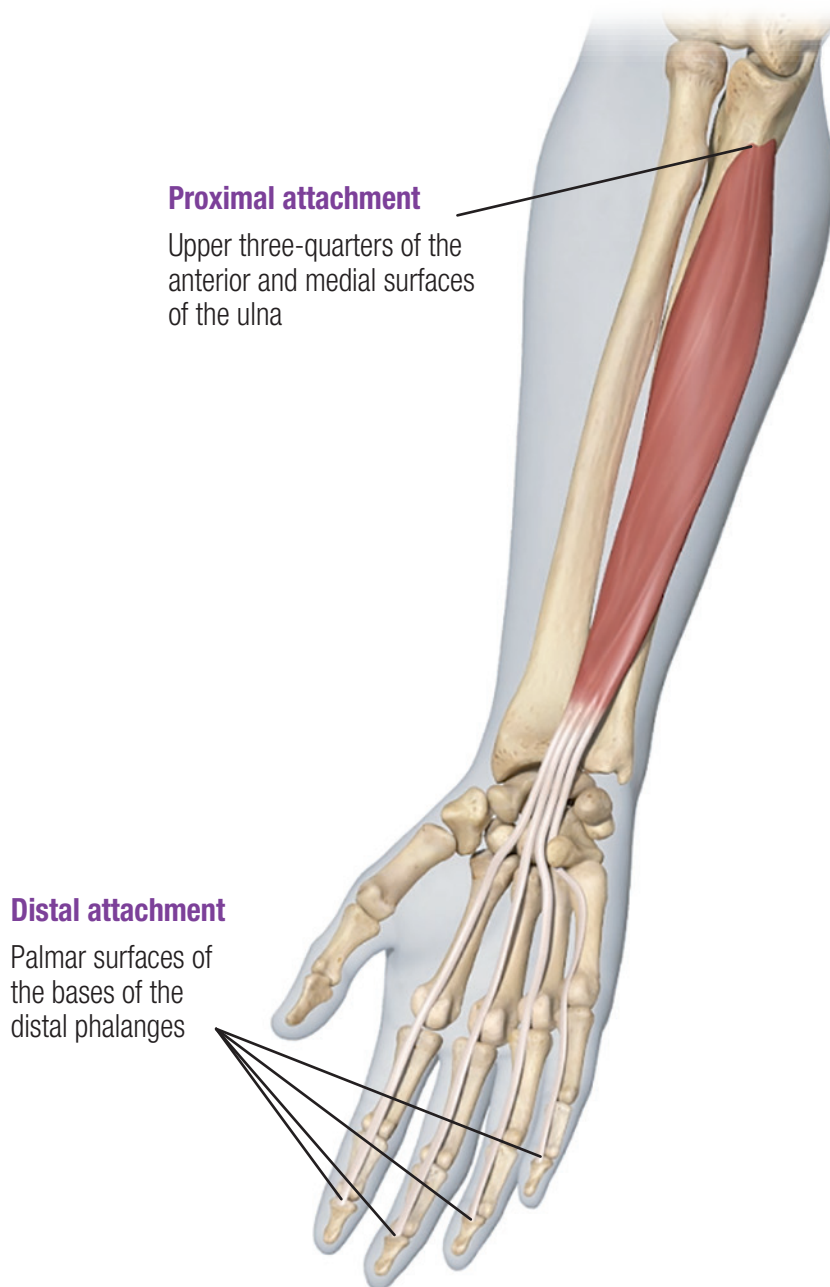
Please see additional Important Safety Information about BOTOX[®] on following pages.

Flexor digitorum profundus

► BOTOX[®] dose: 30 Units to 50 Units (1 site)

Muscle action¹⁹

Primarily finger flexion (only muscle capable of flexing the distal interphalangeal joints), but can also flex any or all of the joints over which it passes



IMPORTANT SAFETY INFORMATION (continued)

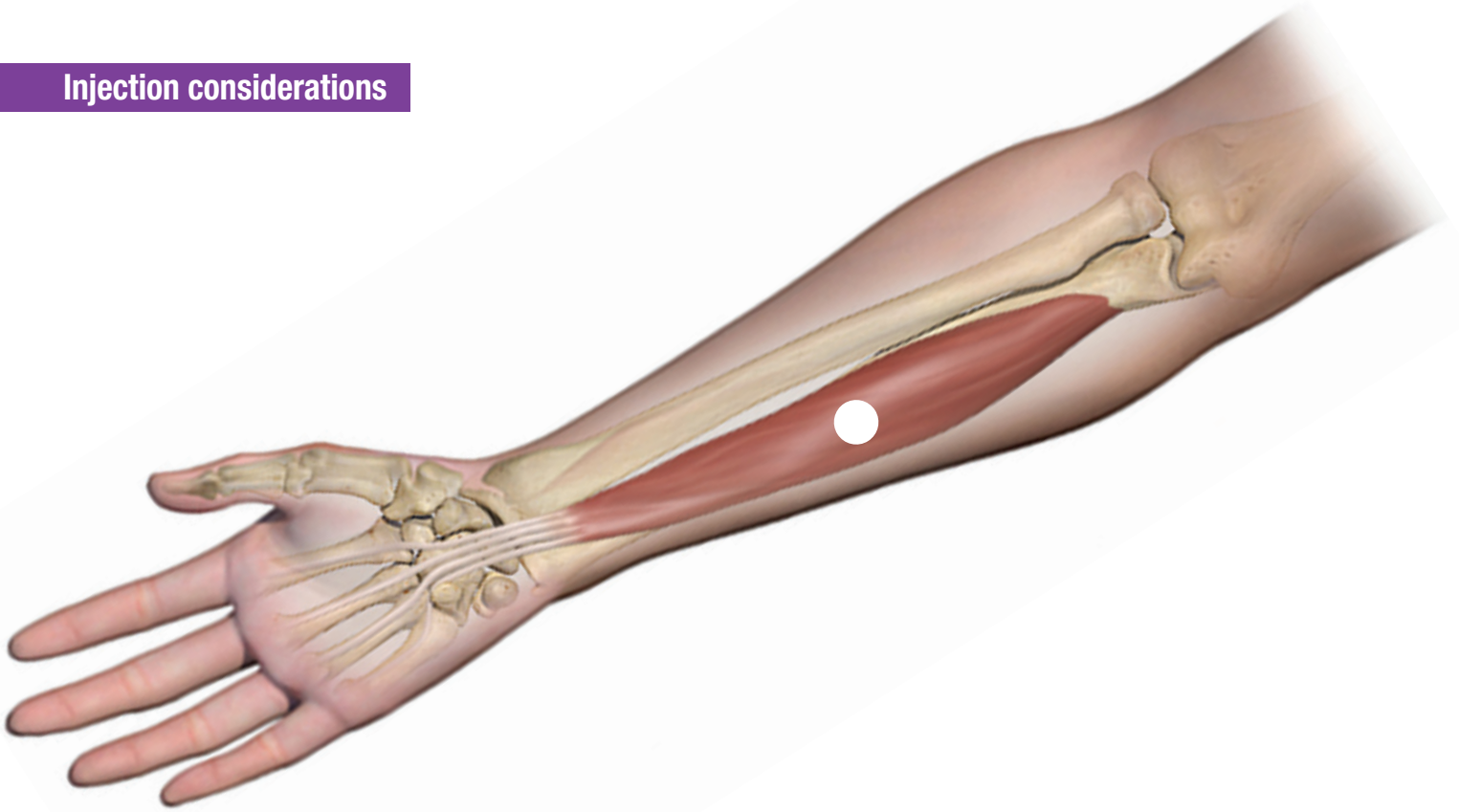
WARNINGS AND PRECAUTIONS (continued)

Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such a reaction occurs, further injection of BOTOX[®] should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent, and consequently the causal agent cannot be reliably determined.

Flexor digitorum profundus (continued)

Injection considerations



- If possible, position the elbow bent and forearm vertical
- Consider injecting the mid forearm, proximal toward the elbow, at the largest part of the muscle. Note that the muscle is deeper in the anatomy of the arm
- If there is more spasticity in fingers 2 and 3, advance your needle more laterally
- The finger flexors are located in the middle half of the forearm. Target this muscle when the distal interphalangeal joints are closed
- Be aware of the surrounding nerves, arteries, and veins that are in the trajectory of the needle path

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Dysphagia and Breathing Difficulties

Treatment with BOTOX[®] and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Pulmonary Effects of BOTOX[®] in Patients With Compromised Respiratory Status Treated for Spasticity

Patients with compromised respiratory status treated with BOTOX[®] for adult spasticity should be monitored closely.

Please see additional Important Safety Information about BOTOX[®] on following pages.

Flexor digitorum superficialis (sublimis)

► BOTOX[®] dose: 30 Units to 50 Units (1 site)

Muscle action¹⁹

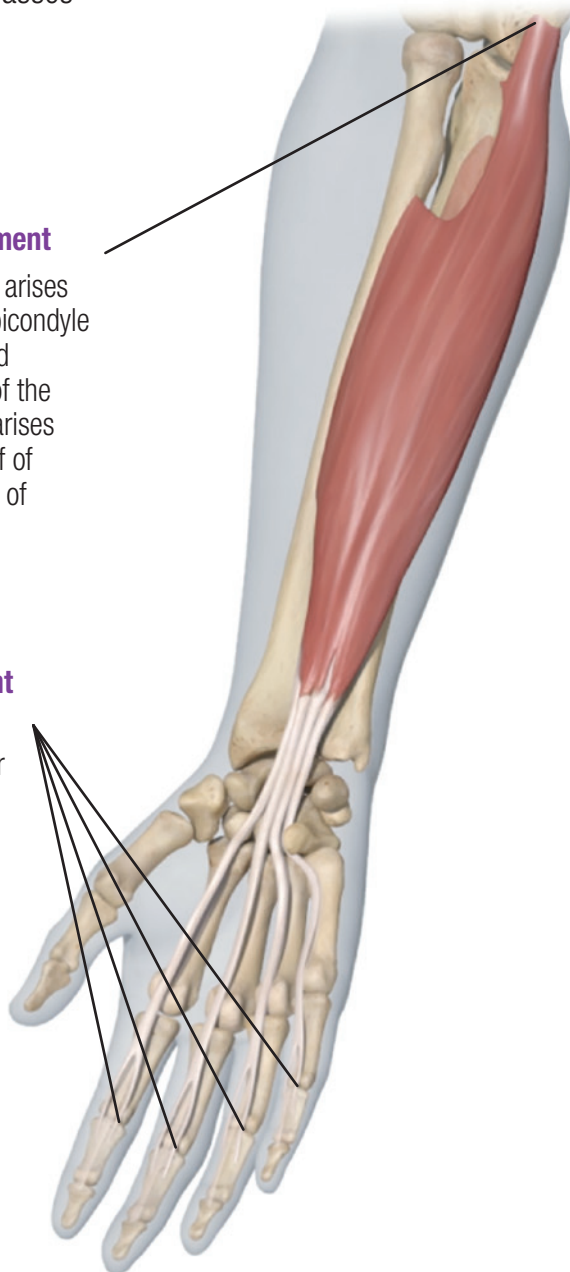
Primarily finger flexion of proximal interphalangeal (PIP) joints, but can also flex any or all of the joints over which it passes

Proximal attachment

Humeroulnar head arises from the medial epicondyle of the humerus and coronoid process of the ulna. Radial head arises from the upper half of the anterior border of the radius

Distal attachment

Medial and lateral sides of the palmar surface of the middle phalanges

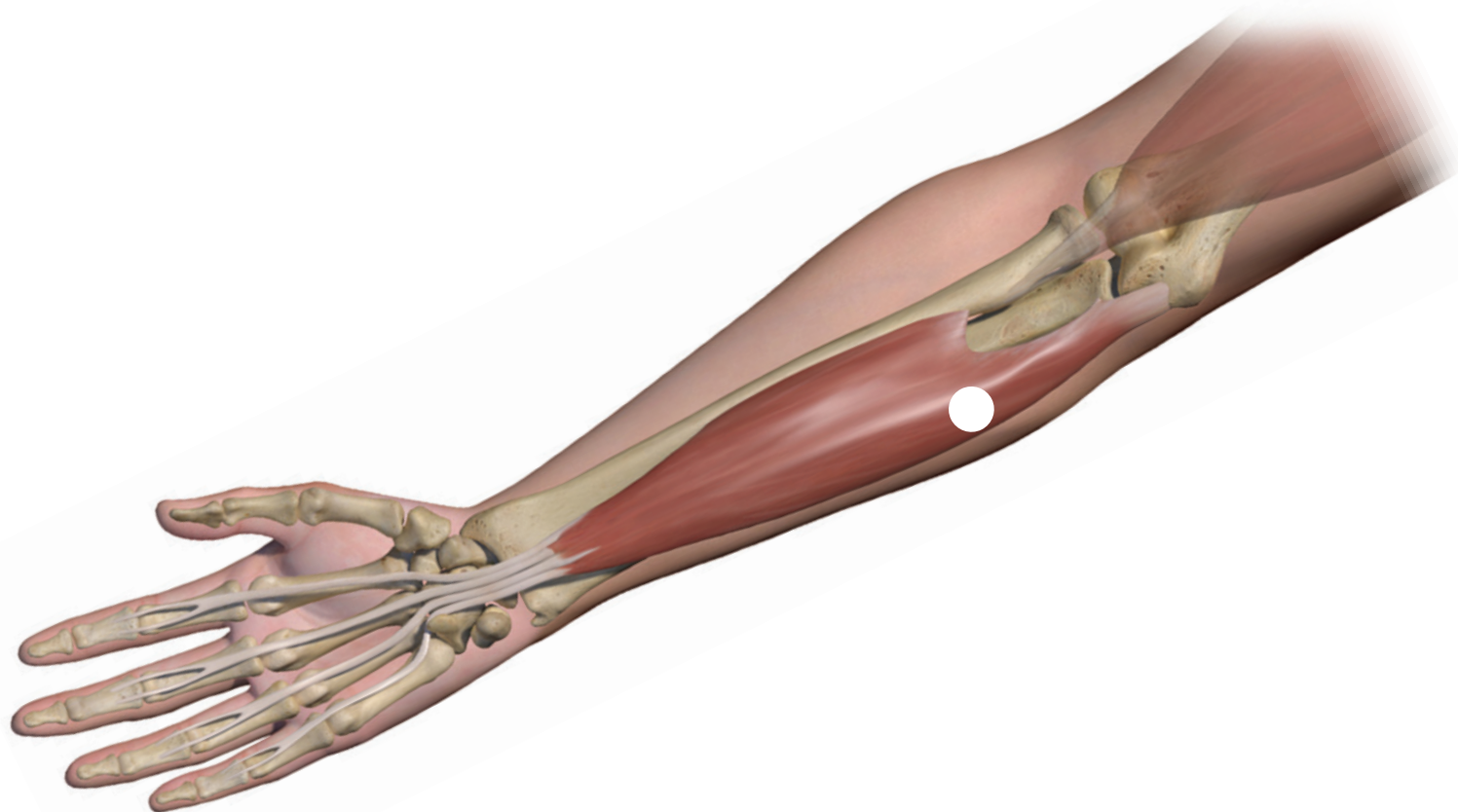


Other muscle involved in finger flexion (proximal interphalangeal joints)

- Flexor digitorum profundus

Flexor digitorum superficialis (sublimis) (continued)

Injection considerations



- Target this muscle when the proximal interphalangeal (PIP) joints are open and spastic
- The finger flexors are located in the middle third to half of the forearm. Localization of this muscle may be difficult
- Passively extend the PIP joints to help localize the muscle. The use of E-Stim is highly recommended
- Once the muscle has been anatomically localized, use EMG and/or E-Stim guidance to further identify the muscle
- If the fingers can be stretched out, it makes identifying the superficialis and profundus with E-Stim easier

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Human Albumin and Transmission of Viral Diseases

This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD, or vCJD have ever been identified for licensed albumin or albumin contained in other licensed products.

Please see additional Important Safety Information about BOTOX[®] on following pages.

Flexor pollicis longus

► BOTOX[®] dose: 20 Units (1 site)

Muscle action¹⁹

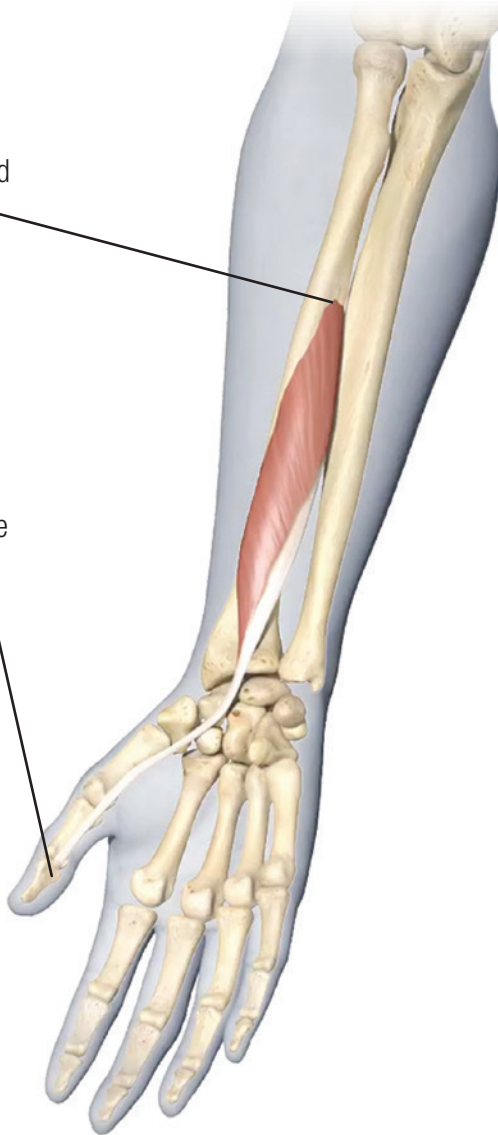
Flexes thumb, but can also be involved in wrist flexion

Proximal attachment

Anterior surface of the radius and the interosseous membrane

Distal attachment

Palmar surface of the base of the distal phalanx of the thumb



IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

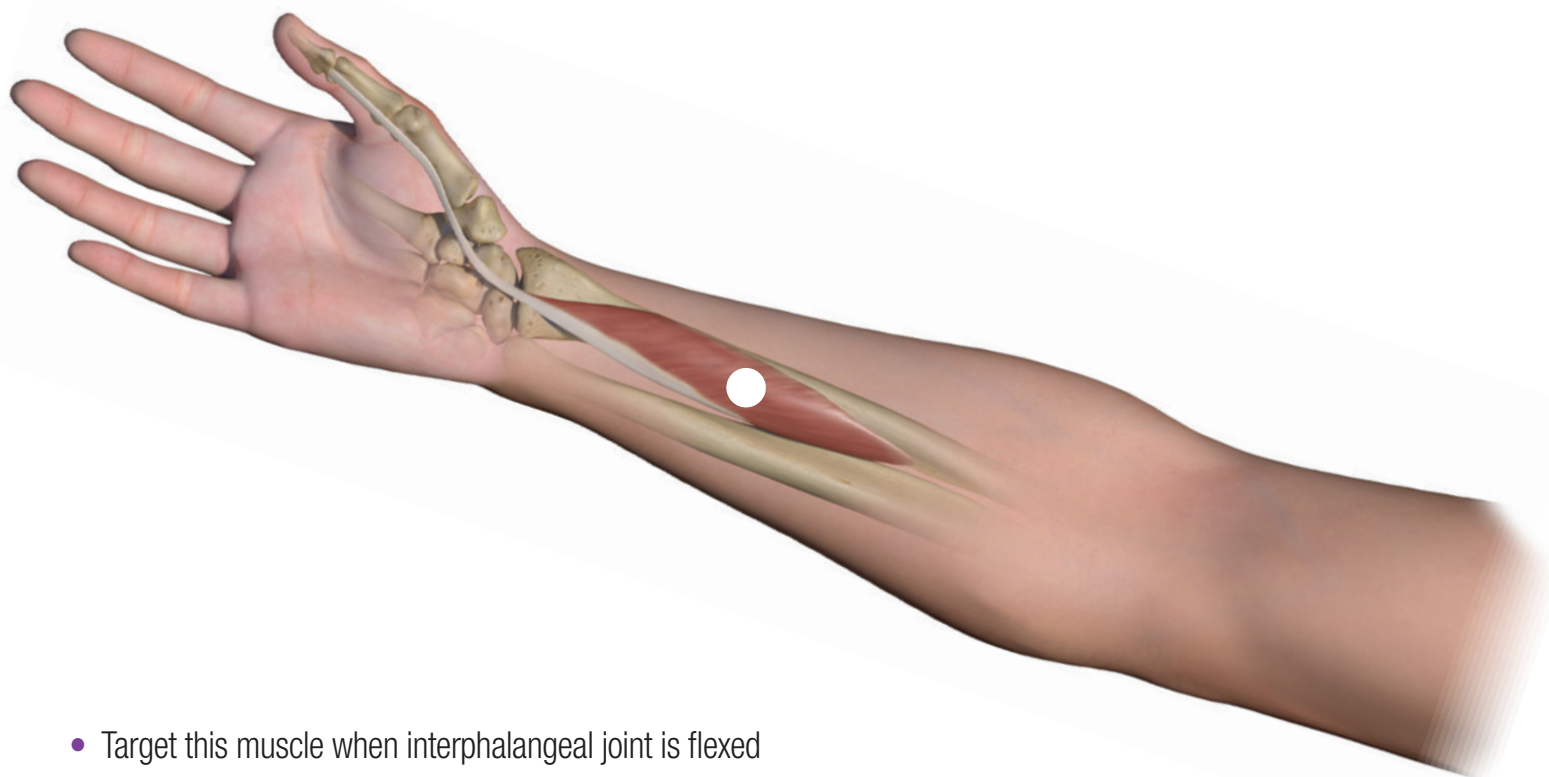
Adverse reactions to BOTOX[®] for injection are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

Adult Upper Limb Spasticity

The most frequently reported adverse reactions following injection of BOTOX[®] for upper limb spasticity include pain in extremity, muscular weakness, fatigue, nausea, and bronchitis.

Flexor pollicis longus (continued)

Injection considerations



- Target this muscle when interphalangeal joint is flexed
- When localizing this muscle, note that it may be more distal in spastic patients
 - Use passive maneuvers to help localize. EMG and/or E-Stim guidance is highly recommended
 - Stabilize the joints prior to injection
- It may be helpful to palpate the radius and then slide to the ulnar side of the radius. Consider inserting the needle volar and lateral to the midline about 2/3 the distance of the forearm from the medial epicondyle

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS (continued)

Postmarketing Experience

Adverse reactions that have been identified during postapproval use of BOTOX[®] are discussed in greater detail in Postmarketing Experience (Section 6.3 of the Prescribing Information).

There have been spontaneous reports of death, sometimes associated with dysphagia, pneumonia, and/or other significant debility or anaphylaxis, after treatment with botulinum toxin. There have also been reports of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including cardiovascular disease. The exact relationship of these events to the botulinum toxin injection has not been established.

Please see additional Important Safety Information about BOTOX[®] on following pages.

Adductor pollicis

► BOTOX[®] dose: 20 Units (1 site)

Muscle action¹⁹

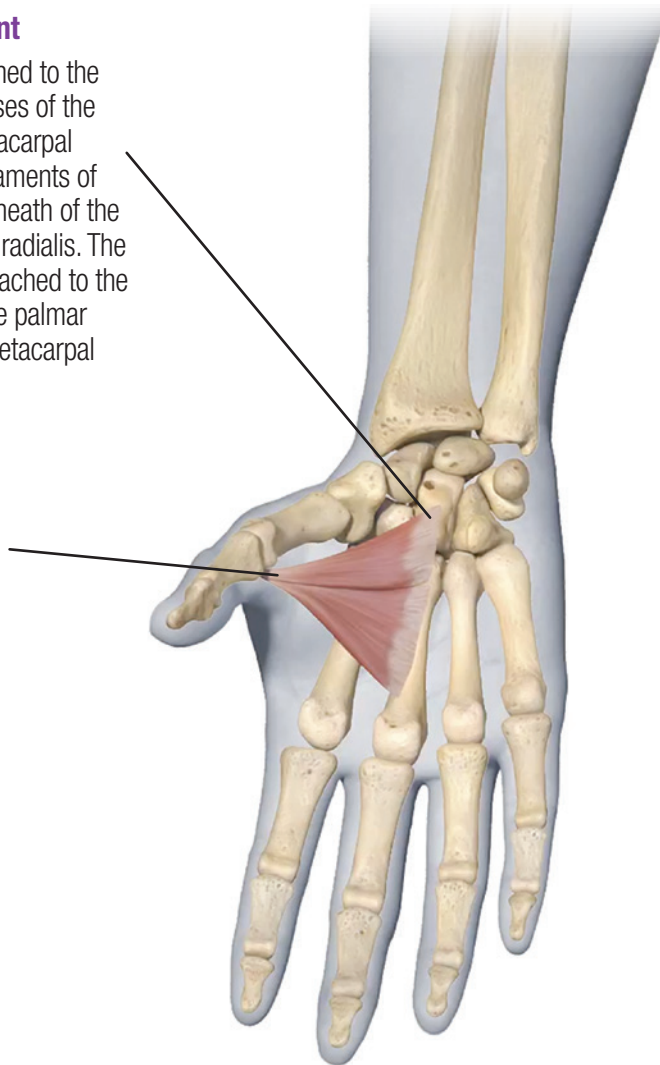
Adducts the thumb

Proximal attachment

Oblique head is attached to the capitate bone, the bases of the second and third metacarpal bones, the palmar ligaments of the carpus, and the sheath of the tendon of flexor carpi radialis. The transverse head is attached to the distal two-thirds of the palmar surface of the third metacarpal

Distal attachment

Base of the proximal phalanx of the thumb



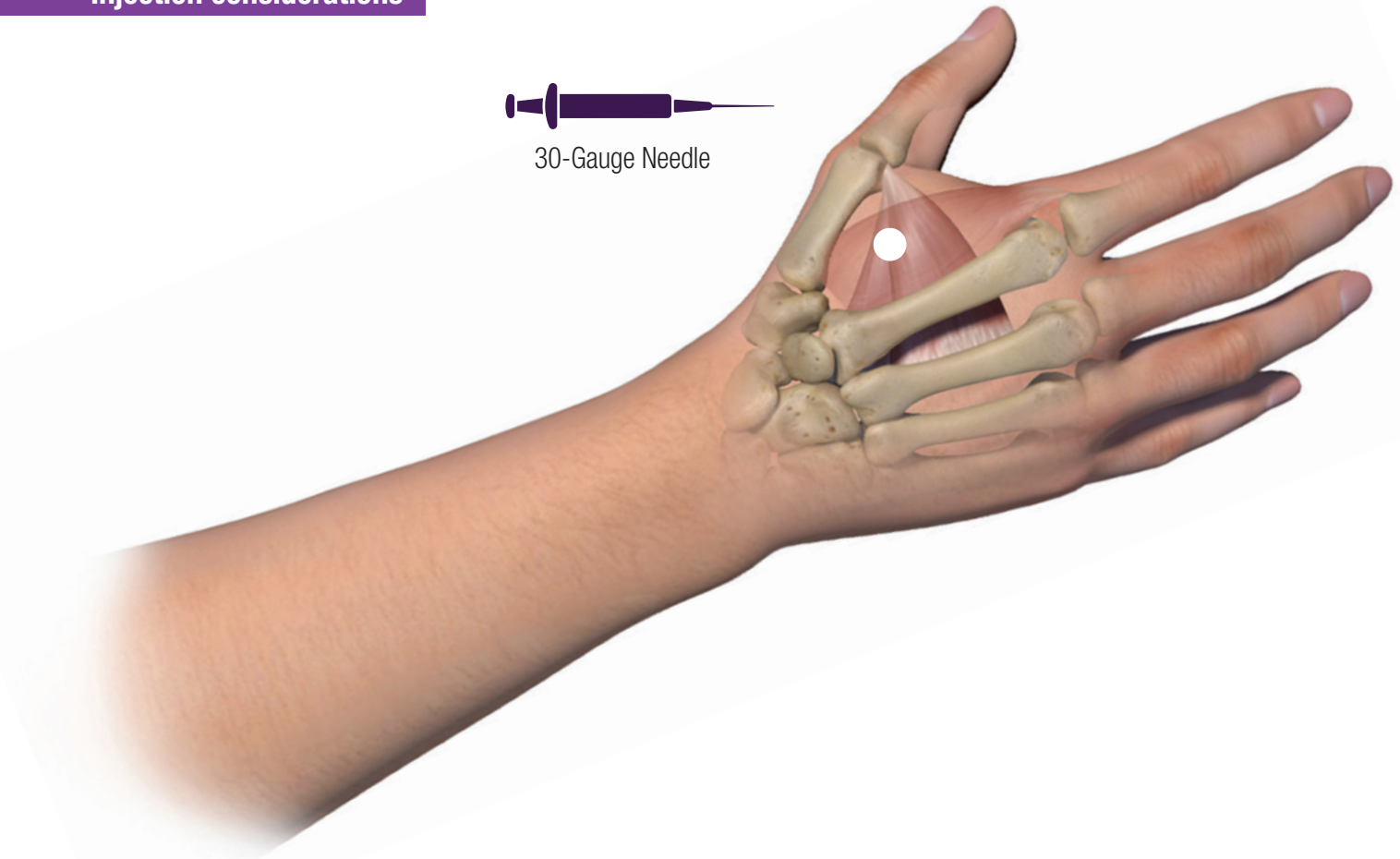
IMPORTANT SAFETY INFORMATION (continued)

DRUG INTERACTIONS

Co-administration of BOTOX[®] and other agents interfering with neuromuscular transmission (eg, aminoglycosides, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX[®] may potentiate systemic anticholinergic effects.

Adductor pollicis (continued)

Injection considerations



- This muscle is most often injected when trying to position the thumb for a wrist/hand orthosis
- Consider inserting the needle from the backside of the hand and injecting quickly to minimize pain
- It is often a painful injection site, so consider the use of a 30-gauge needle

IMPORTANT SAFETY INFORMATION (continued)

CONTRAINDICATIONS

BOTOX[®] is contraindicated in the presence of infection at the proposed injection site(s) and in patients who are hypersensitive to any botulinum toxin product or to any of the components in the formulation.

WARNINGS AND PRECAUTIONS

Spread of Toxin Effect

See Boxed Warning.

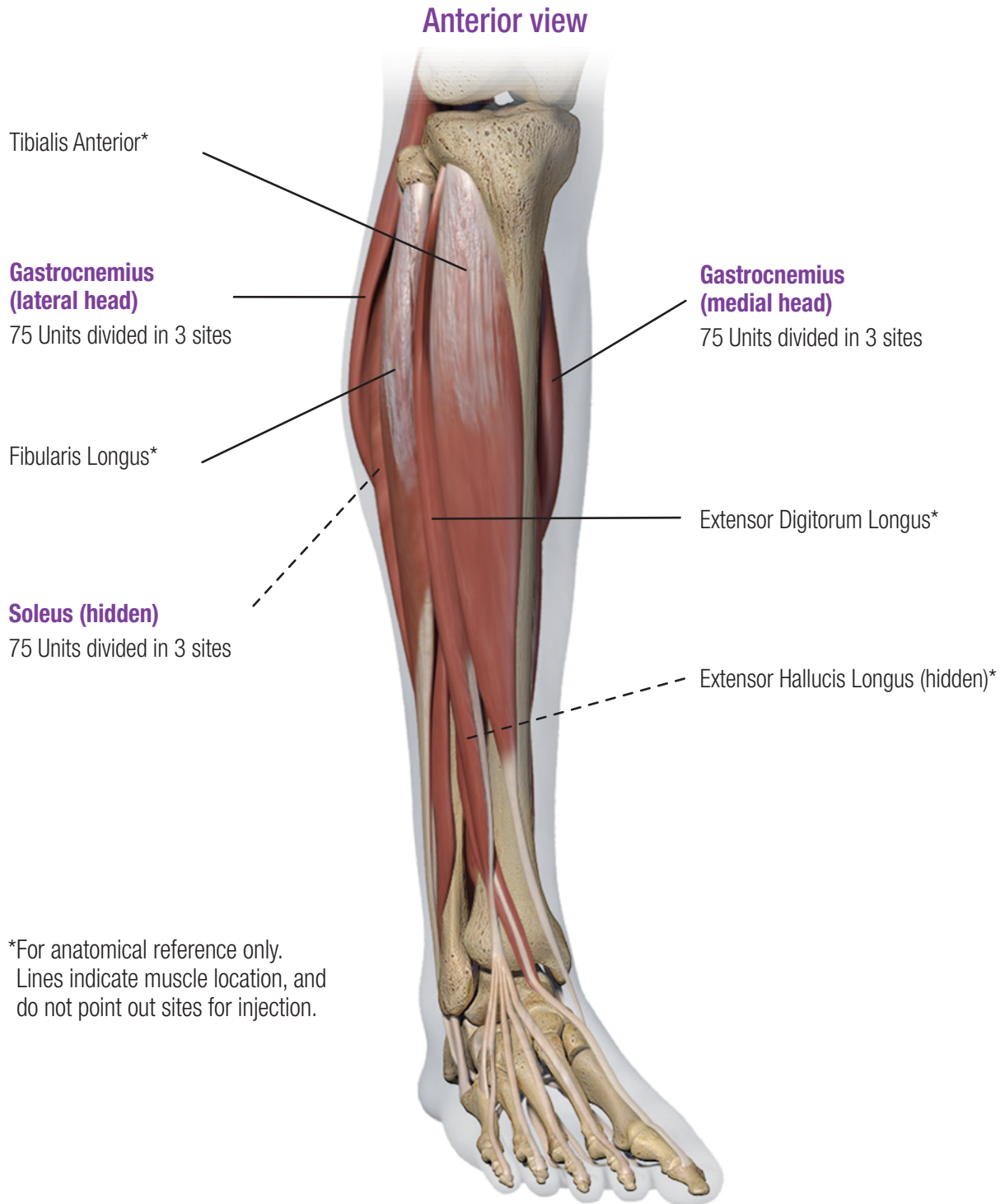
Lack of Interchangeability Between Botulinum Toxin Products

The potency Units of BOTOX[®] are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, Units of biological activity of BOTOX[®] cannot be compared to nor converted into Units of any other botulinum toxin products assessed with any other specific assay method.

Please see additional Important Safety Information about BOTOX[®] on following pages.

Main muscles involved in Adult Lower Limb Spasticity

Muscles listed in purple are those approved for BOTOX[®] injection¹⁸



IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Serious Adverse Reactions With Unapproved Use

Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX[®] injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX[®] to the site of injection and/or adjacent structures.

Gastrocnemius

► BOTOX[®] dose: 75 Units divided in 3 sites (medial head) and 75 Units divided in 3 sites (lateral

Muscle action¹⁹

Involved in plantarflexion and flexing the knee

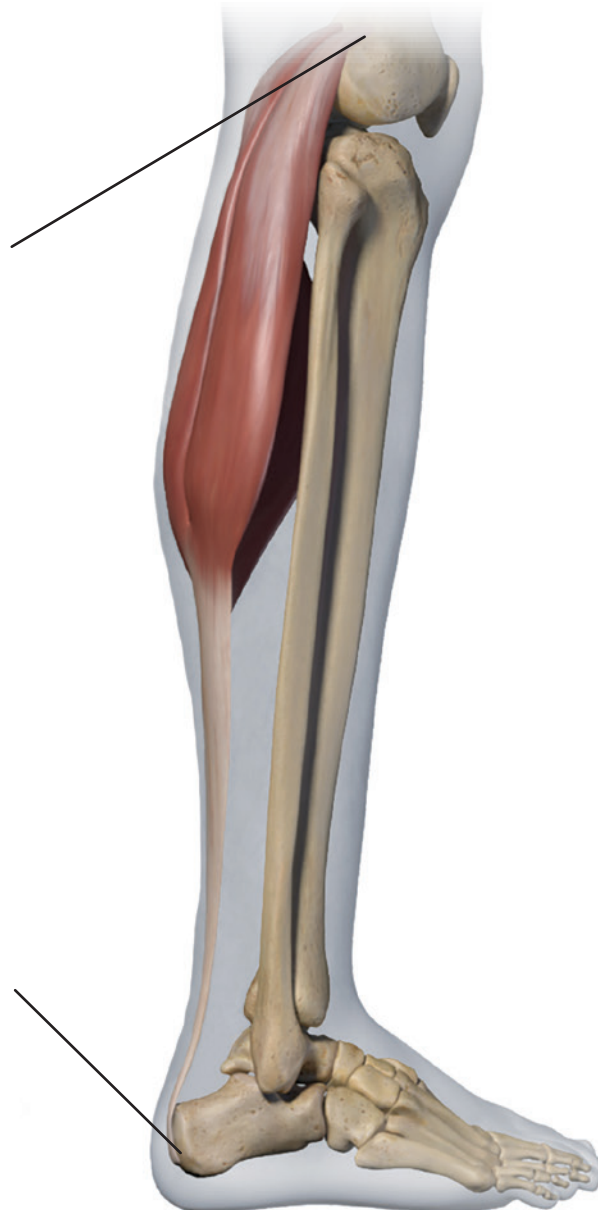
Proximal attachment

Lateral head: Lateral surface of the lateral condyle and to the lower part of the corresponding supracondylar line

Medial head: Popliteal surface of the femur just above the medial condyle

Distal attachment

Posterior surface of calcaneus by calcaneal tendon



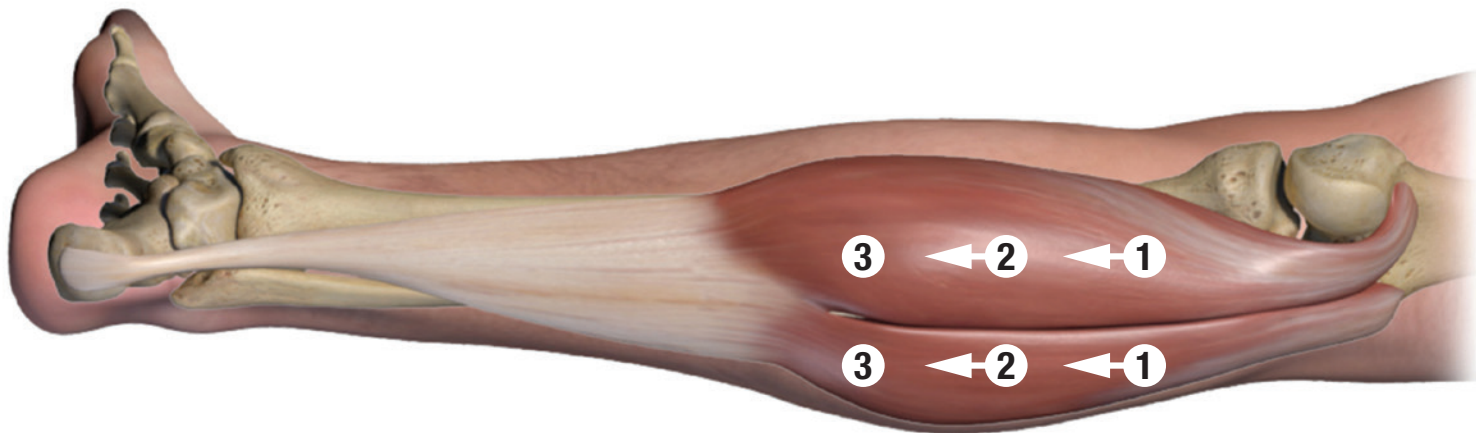
Other muscles involved in plantarflexion

- Soleus
- Tibialis posterior
- Flexor digitorum longus
- Flexor hallucis longus
- Fibularis longus*

*For anatomical reference only.

Gastrocnemius (continued)

Injection considerations



- Gastrocnemius and soleus muscles make up the triceps surae and should be thought of as a complex
- The gastrocnemius crosses both the knee and ankle
- Position patient prone when possible
- Consider following a straight line from proximal to distal in both the medial and lateral heads when injecting the 3 sites
- Avoid going too distal so that the tendinous area is not inadvertently injected
- Gastrocnemius is thinner than the soleus, so consider needle depth carefully

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Increased Risk of Clinically Significant Effects With Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis (ALS), or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with known or unrecognized neuromuscular disorders or neuromuscular junction disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from therapeutic doses of BOTOX[®] (see *Warnings and Precautions*).

Please see additional Important Safety Information about BOTOX[®] on following pages.

Soleus

► BOTOX[®] dose: 75 Units divided in 3 sites

Muscle action¹⁹

Involved in plantarflexion

Proximal attachment

Posterior surface of the head and proximal quarter of the shaft of the fibula, soleal line and middle third of the medial border of the tibia, and the interosseous membrane

Distal attachment

Posterior surface of calcaneus by calcaneal tendon



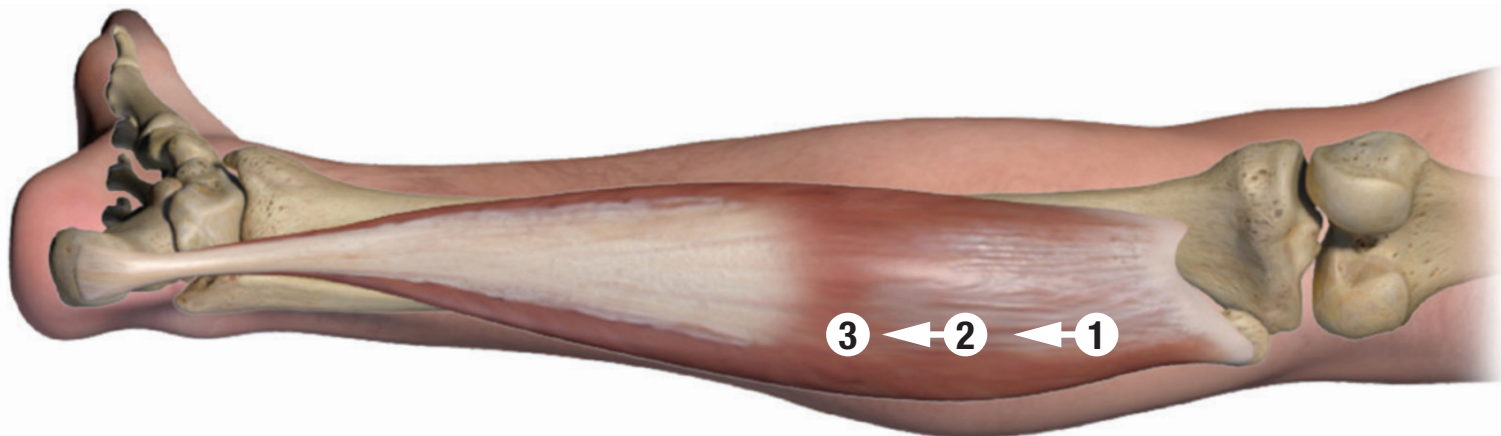
Other muscles involved in plantarflexion

- Gastrocnemius
- Tibialis posterior
- Flexor digitorum longus
- Flexor hallucis longus
- Fibularis longus*

*For anatomical reference only.

Soleus (continued)

Injection considerations



- Soleus and gastrocnemius muscles make up the triceps surae and should be thought of as a complex
- Position patient prone when possible
 - Activate the muscle with the knee flexed and have the patient plantarflex
- The soleus is deep and distal to the gastrocnemius, slightly lateral to the midline down the long axis of the leg
- Consider following a straight line from proximal to distal when injecting the 3 sites
- Consider advancing the needle to avoid further skin punctures
- Avoid going too distal to avoid the tendinous area. Stay above the midcalf

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Pulmonary Effects of BOTOX[®] in Patients With Compromised Respiratory Status Treated for Spasticity

Patients with compromised respiratory status treated with BOTOX[®] for adult spasticity should be monitored closely.

Bronchitis and Upper Respiratory Tract Infections in Patients Treated for Spasticity

Bronchitis was reported more frequently as an adverse reaction in adult patients treated for upper limb spasticity with BOTOX[®] (3% at 251 Units to 360 Units total dose) compared to placebo (1%). In adult patients with reduced lung function treated for upper limb spasticity, upper respiratory tract infections were also reported more frequently as adverse reactions in patients treated with BOTOX[®] (11% at 360 Units total dose; 8% at 240 Units total dose) compared to placebo (6%). In adult patients treated for lower limb spasticity, upper respiratory tract infections were reported more frequently as an adverse reaction in patients treated with BOTOX[®] (2% at 300 Units to 400 Units total dose), compared to placebo (1%).

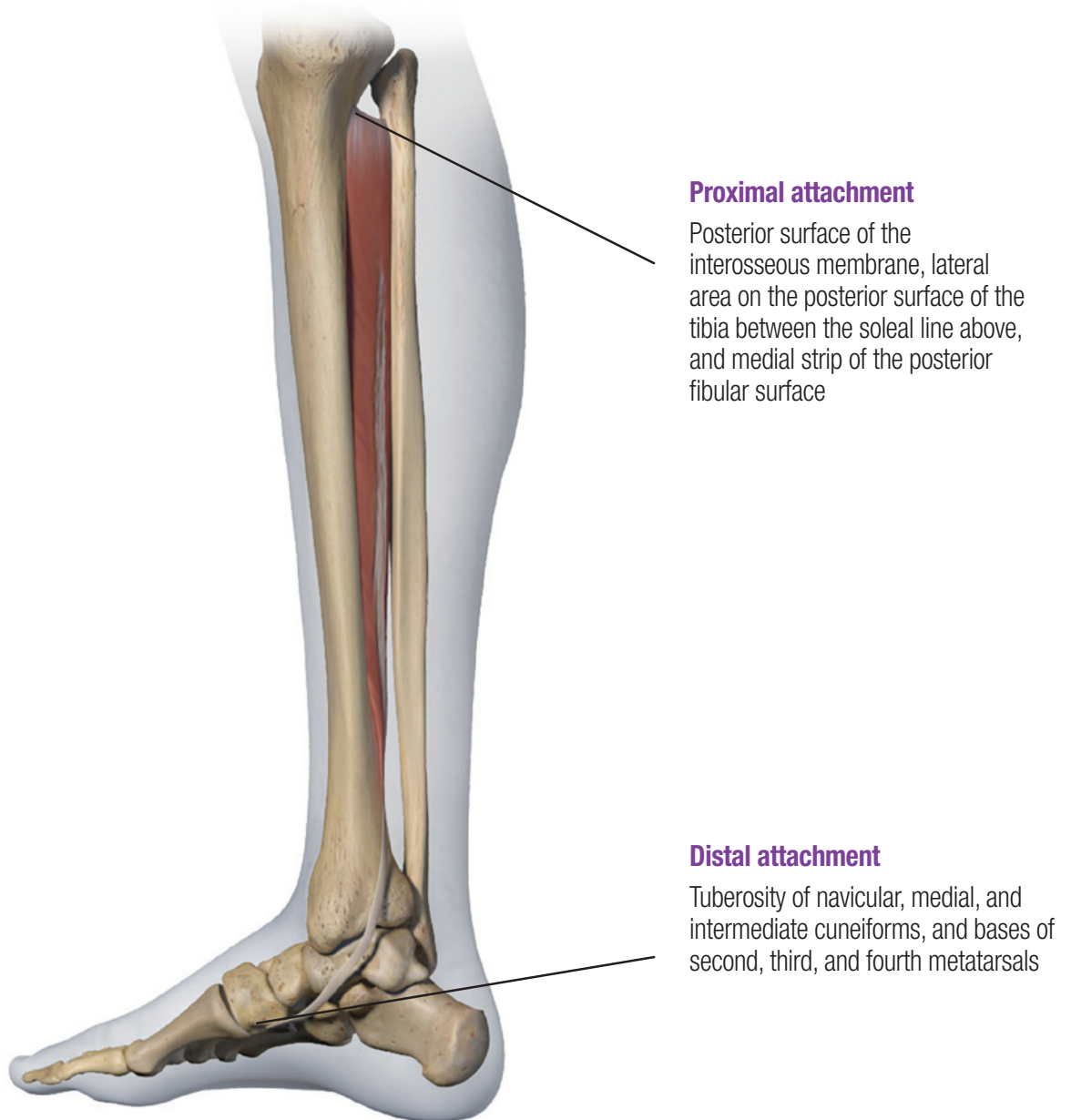
Please see additional Important Safety Information about BOTOX[®] on following pages.

Tibialis posterior

► BOTOX[®] dose: 75 Units divided in 3 sites

Muscle action^{19,23}

Involved in plantarflexion and can also invert and adduct the foot



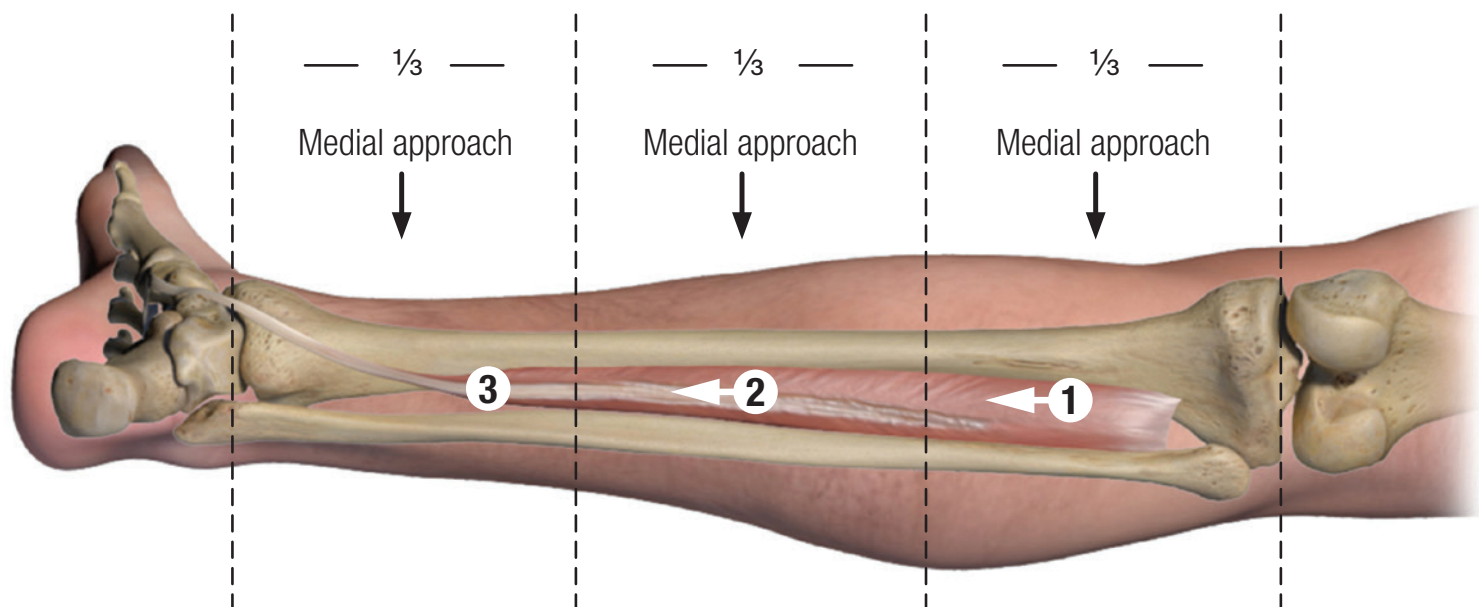
Other muscles involved in plantarflexion and/or foot inversion

- Gastrocnemius (plantarflexion only)
- Soleus (plantarflexion only)
- Flexor digitorum longus
- Flexor hallucis longus²⁴
- Fibularis longus (plantarflexion only)*
- Tibialis anterior (foot inversion only)*

*For anatomical reference only.

Tibialis posterior (continued)

Injection considerations



- Position the patient supine with his/her leg extended, when possible
 - Recommend using established guidance techniques as the muscle may be difficult to locate
- This muscle runs the length of the tibia so divide the leg into thirds
- Consider even distribution from proximal to distal when injecting the 3 sites
- Use a medial approach to avoid the neurovascular bundle

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

Adverse reactions to BOTOX[®] for injection are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

Adult Upper Limb Spasticity

The most frequently reported adverse reactions following injection of BOTOX[®] for upper limb spasticity include pain in extremity, muscular weakness, fatigue, nausea, and bronchitis.

Adult Lower Limb Spasticity

The most frequently reported adverse reactions following injection of BOTOX[®] for lower limb spasticity include arthralgia, back pain, myalgia, upper respiratory tract infection, and injection-site pain.

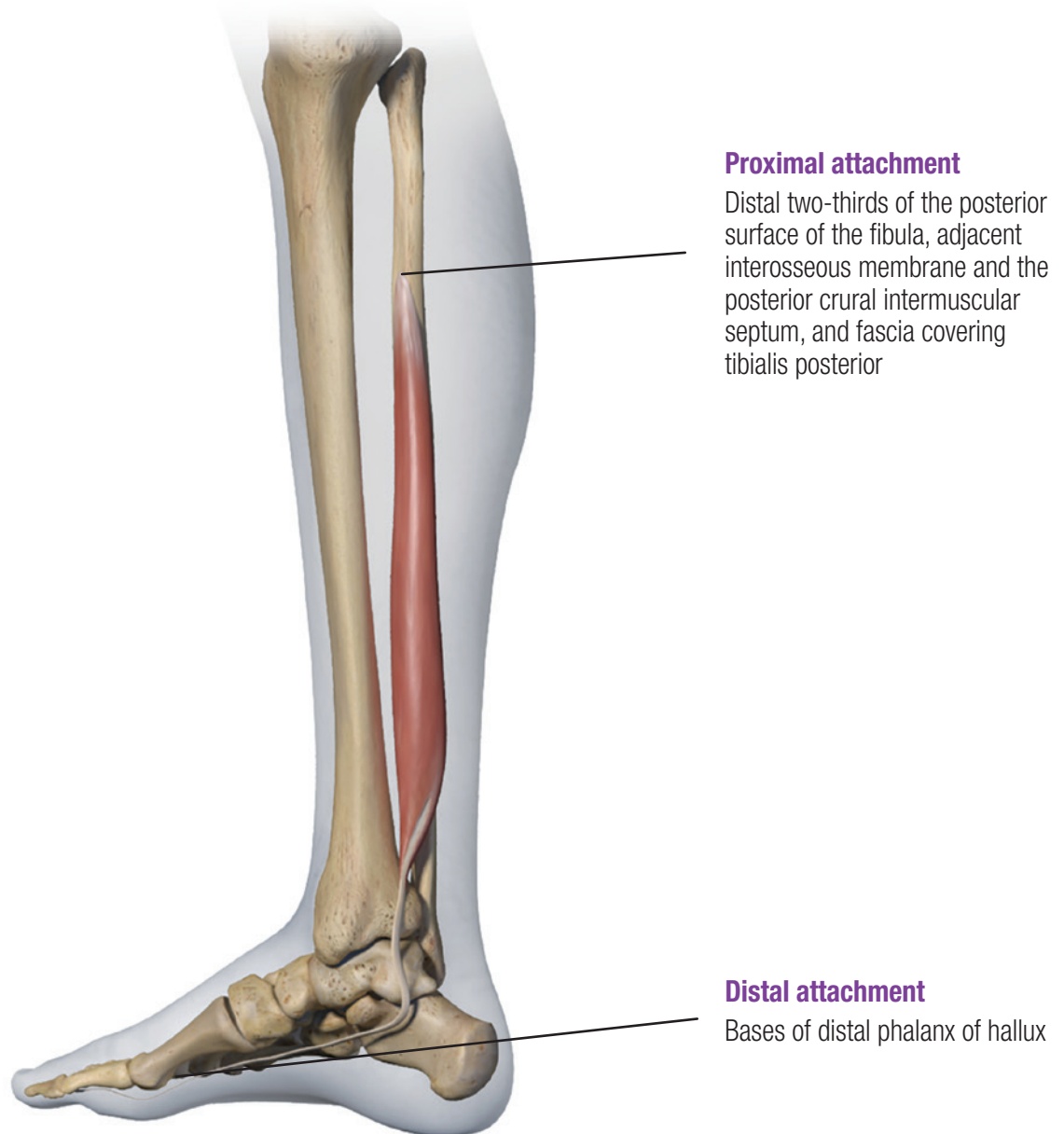
Please see additional Important Safety Information about BOTOX[®] on following pages.

Flexor hallucis longus

► BOTOX[®] dose: 50 Units divided in 2 sites

Muscle action^{19,24}

Involved in flexion of hallux, plantarflexion, and foot inversion



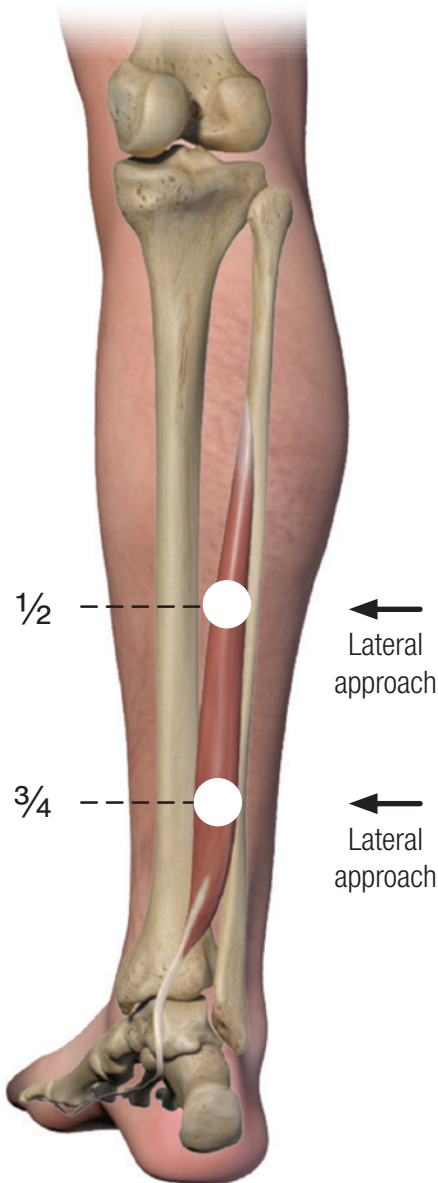
Other muscles involved in plantarflexion and/or foot inversion

- Gastrocnemius (plantarflexion only)
- Soleus (plantarflexion only)
- Tibialis posterior²³
- Flexor digitorum longus
- Fibularis longus (plantarflexion only)*
- Tibialis anterior (foot inversion only)*

*For anatomical reference only.

Flexor hallucis longus (continued)

Injection considerations



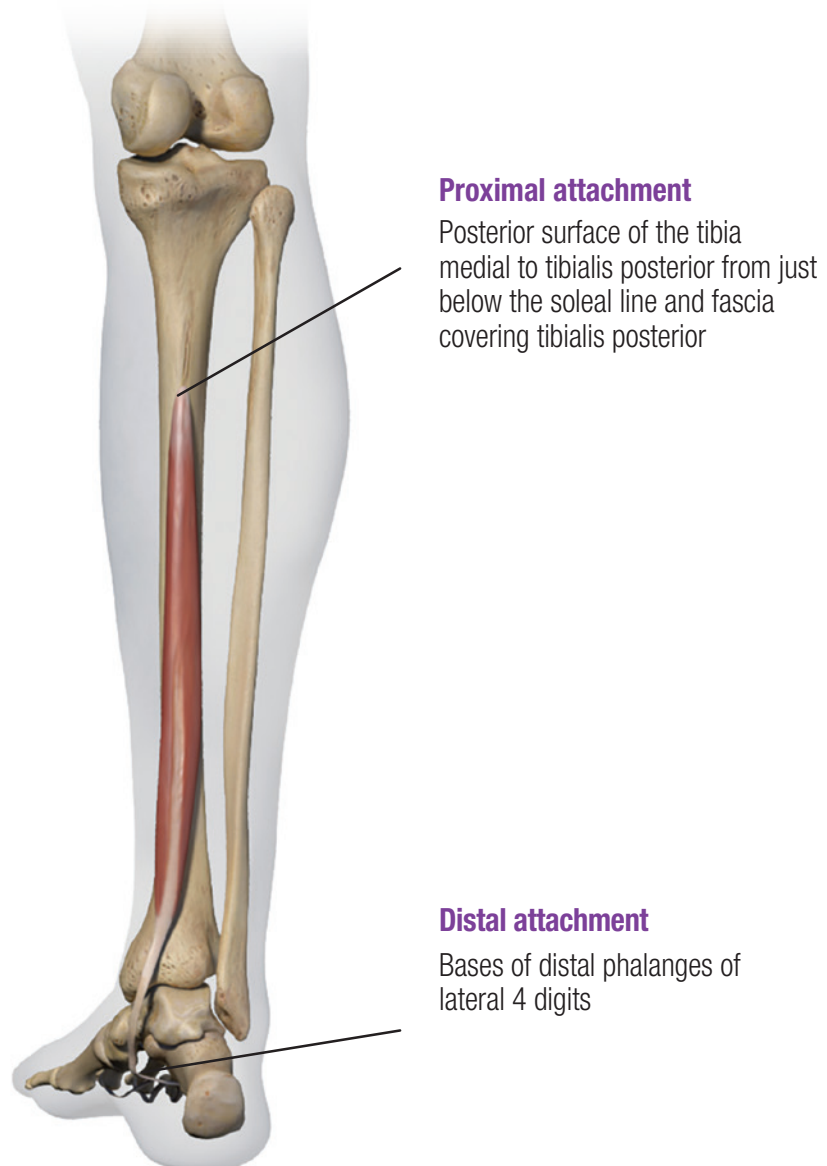
- Position the patient supine, when possible
- This muscle starts at the lateral side of the leg and comes across the medial side at the ankle, but closer to the tendon than the bone
- Based on the anatomical structure, consider a lateral approach
- Consider targeting 1/3 to 2/3 proximal, respectively, to the lateral malleolus, 1/3 of the way up from the back of the heel to the knee when injecting the 2 sites
 - Consider placing the needle midway to 3/4 distally down the leg
- Inject this muscle when the great toe has flexion spasticity

Flexor digitorum longus

► BOTOX[®] dose: 50 Units divided in 2 sites¹⁸

Muscle action^{19,24}

Involved in flexion of lateral 4 digits, plantarflexion, and foot inversion



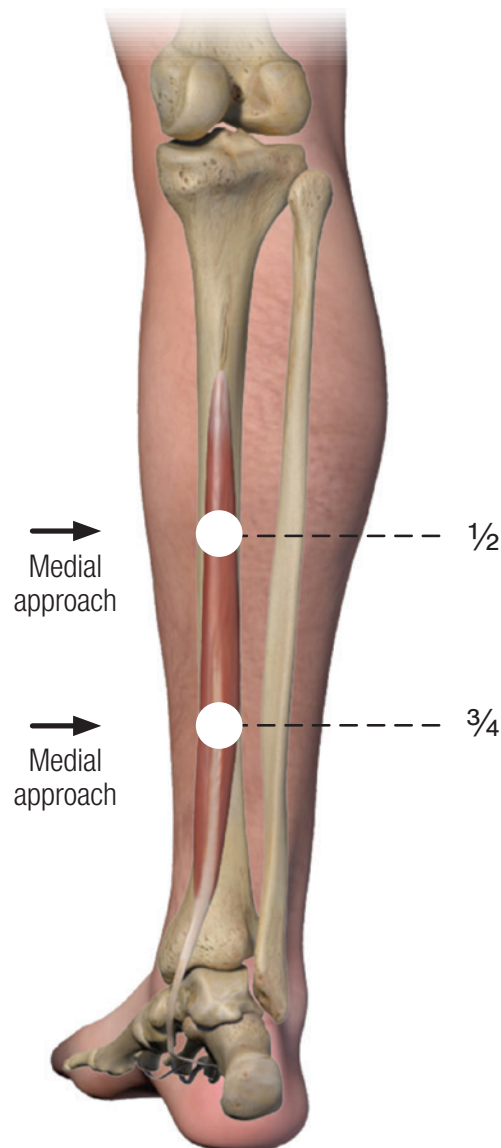
Other muscles involved in plantarflexion and/or foot inversion

- Gastrocnemius (plantarflexion only)
- Soleus (plantarflexion only)
- Tibialis posterior
- Flexor hallucis longus
- Fibularis longus (plantarflexion only)*
- Tibialis anterior (foot inversion only)*

*For anatomical reference only.

Flexor digitorum longus (continued)

Injection considerations



- The patient can be positioned supine, prone, or sitting
- This muscle starts at the medial part of the leg and continues laterally to the foot
- Have patients bend their toes while using EMG to help localize the muscle. With E-Stim you want them to relax the muscle, not bend their toes
- Consider targeting 1/2 and 3/4 distally down the leg when injecting the 2 sites

BOTOX[®] Treatment Framework documentation

Utilize the BOTOX[®] Treatment Framework when evaluating your next Adult Spasticity patient



The right goals

Patient name:

Posture(s):

- | | | |
|--|---------------------------------------|---|
| <input type="checkbox"/> Flexed elbow | <input type="checkbox"/> Flexed wrist | <input type="checkbox"/> Flexed fingers |
| <input type="checkbox"/> Thumb in palm | <input type="checkbox"/> Flexed ankle | <input type="checkbox"/> Flexed toes |

Symptoms:

Goals:

- ☐ Repeat goals back to patient

Expectations:

- ☐ BOTOX[®] is not a cure, nor a substitute for usual standard of care
- ☐ Muscles/dose may need to be adjusted for future injections
- ☐ Fine needles are used during injections
- ☐ Patient should return for a 4- to 6-week follow-up evaluation
- ☐ Review insurance plans to determine out-of-pocket costs and use of potential savings programs

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Serious Adverse Reactions With Unapproved Use

Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX[®] injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX[®] to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX[®]. The safety and effectiveness of BOTOX[®] for unapproved uses have not been established.

Please see additional Important Safety Information about BOTOX[®] on following pages.

BOTOX[®] Treatment Framework documentation (continued)

4- to 6-week follow-up



The right plan

Percentage of goals achieved:

Improvements:

Patient comments:

Potential adjustments in muscles/BOTOX[®] dose:

☐ Patient scheduled for next treatment session

IMPORTANT SAFETY INFORMATION (continued) **WARNINGS AND PRECAUTIONS (continued)**

Hypersensitivity Reactions

Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, dyspnea. If such a reaction occurs, further injection of BOTOX[®] should be discontinued and appropriate medical therapy immediately instituted. One fatal anaphylaxis has been reported in which lidocaine was used as the diluent, and consequently the causal agent cannot be reliably determined.

Please see additional Important Safety Information about BOTOX[®] on following pages.

BOTOX[®] Treatment Framework documentation (continued)

4- to 6-week follow-up



The right plan

Percentage of goals achieved:

Improvements:

Patient comments:

Potential adjustments in muscles/BOTOX[®] dose:

☐ Patient scheduled for next treatment session

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Increased Risk of Clinically Significant Effects With Pre-existing Neuromuscular Disorders

Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis (ALS), or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with known or unrecognized neuromuscular disorders or neuromuscular junction disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from therapeutic doses of BOTOX[®] (see *Warnings and Precautions*).

Dysphagia and Breathing Difficulties

Treatment with BOTOX[®] and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Dilution and reconstitution

Follow general dilution instructions for BOTOX[®] vials (100 Units and 200 Units)¹

100-Unit BOTOX [®] Vial		
0.9% Sodium Chloride* per vial	Dose per 1 mL syringe	Dose per 0.1 mL
1 mL	100 Units	10 Units
2 mL	50 Units	5 Units
4 mL	25 Units	2.5 Units
8 mL	12.5 Units	1.25 Units
10 mL	10 Units	1 Unit

200-Unit BOTOX [®] Vial		
0.9% Sodium Chloride* per vial	Dose per 1 mL syringe	Dose per 0.1 mL
1 mL	200 Units	20 Units
2 mL	100 Units	10 Units
4 mL	50 Units	5 Units
8 mL	25 Units	2.5 Units
16 mL	12.5 Units	1.25 Units
20 mL	10 Units	1 Unit

*Preservative-free 0.9% Sodium Chloride Injection, USP only.

- The recommended dilution is 200 Units/4 mL or 100 Units/2 mL with preservative-free 0.9% Sodium Chloride Injection, USP (see table above)
- Administer the 200-Unit vial or 100-Unit vial of BOTOX[®] within 24 hours after reconstitution in the vial
- Unused reconstituted BOTOX[®] should be stored in a refrigerator (2°C to 8°C) for up to 24 hours until time of use
- BOTOX[®] vials are for single-dose only. Discard any unused portion
- Unopened vials of BOTOX[®] should be stored in a refrigerator (between 2°C to 8°C or 36°F to 46°F) for up to 36 months

Ensure your office is ready for your first BOTOX[®] injections

- Set up an Allergan[®] account for BOTOX[®] ordering (1-800-811-4148)
- Ensure there is a refrigerator to store BOTOX[®] vials
- Make sure materials have been ordered:
 - 100- and/or 200-Unit BOTOX[®] vials
 - 25- to 30-gauge needles for superficial muscles
 - 22-gauge needles for deeper muscles
 - 21-gauge, 2-inch needles for reconstitution
 - 1-mL syringes for injections
 - Appropriately sized syringes for reconstitution
 - Single-use vials of preservative-free, 0.9% sodium chloride (saline)
 - Alcohol swabs for cleaning the rubber stoppers on the saline and BOTOX[®] vials
 - Adhesive bandages
 - Muscle localization guidance equipment if needed
- Review the BOTOX[®] reconstitution process
- Confirm insurance plan requirements for scheduled patients to ensure appropriate chart-documentation and prior-authorization steps are met (if required)
- Call to remind patients of their scheduled injections

IMPORTANT SAFETY INFORMATION (continued)

ADVERSE REACTIONS

Adverse reactions to BOTOX[®] for injection are discussed in greater detail in the following sections: *Boxed Warning*, *Contraindications*, and *Warnings and Precautions*.

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Adult Lower Limb Spasticity

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Postmarketing Experience

Adverse reactions that have been identified during postapproval use of BOTOX[®] are discussed in greater detail in Postmarketing Experience (Section 6.3 of the Prescribing Information).

Reimbursement Business Advisor (RBA)

- Works with practices to identify and focus on operational needs (including reimbursement support) that can facilitate the safe and effective use of BOTOX[®] treatment
- Provides in-person insights regarding BOTOX[®] office processes from the time the patient is first identified through follow-up care

Ask your Allergan[®] Representative how an RBA can help

BOTOX[®] Savings Program

Patients may

PAY as little as **\$0** for BOTOX[®] treatments



Here's how:

- Most insurance plans cover the majority of BOTOX[®] costs. However, some commercially insured adult patients with spasticity may still owe a co-pay*
- On average, the out-of-pocket cost for BOTOX[®] for commercially insured patients is \$184 per 12-week treatment. There may be additional costs for the procedure, which will vary by healthcare provider and insurance*
- The BOTOX[®] Savings Program can reimburse eligible patients up to \$1000 per treatment to help with these remaining costs*

 **Patients can text[†] SAVE to 27747**
or visit BOTOXSavingsProgram.com to get started 

*Restrictions and maximum savings limits apply. Patient out-of-pocket expense may vary. Offer not valid for patients enrolled in Medicare, Medicaid, or other federal or state healthcare programs. Please see full terms and conditions at BOTOXSavingsProgram.com.

[†]See Privacy & Terms: BOTOXSavingsProgram.com/eligibility. Message & data rates may apply. Message frequency may vary. Text HELP for help, STOP to end.

IMPORTANT SAFETY INFORMATION (continued)

DRUG INTERACTIONS

Co-administration of BOTOX[®] and other agents interfering with neuromuscular transmission (eg, aminoglycosides, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX[®] may potentiate systemic anticholinergic effects. The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX[®].

Please see accompanying full Prescribing Information including Boxed Warning and Medication Guide.

Helpful phone numbers and websites



ORDERING

AllerganDirect.com or call 1-800-44-BOTOX (1-800-442-6869)

CUSTOMER SERVICE

1-800-44-BOTOX (1-800-442-6869)

ALLERGAN[®] MEDICAL INFORMATION LINE

1-800-433-8871

PATIENT FINANCIAL ASSISTANCE

For commercially insured patients: BOTOXSavingsProgram.com

PROFESSIONAL EDUCATION & RESOURCES

For injection training opportunities: Contact your Allergan[®] Representative

For Reimbursement Business Advisors: Contact your Allergan[®] Representative

For injection and reconstitution videos, plus downloadable patient education and more: BOTOXAcademy.com

Please see Important Safety Information, including Boxed Warning, inside.