#### **Esthetics Procedures List - October 2024**

This document reflects recommendations by the Esthetics Council and does not reflect any deliberation or decisionmaking by an Alaska professional licensing work group or board. This document is a working draft and does not define current Alaska requirements.

This chart may be used in whole or in part to assist the Alaska Medical Spa Services Work Group and related Alaska professional licensing boards understand the procedures in question, as well as assist in clarifying current and future scope of practice of:

- Currently licensed estheticians under the Board of Barbers and Hairdressers
- Future advanced esthetician licensees (requires statute change)
- Persons performing these procedures under **medical supervision:** In the context of this document, "medical supervision" means onsite supervision by a physician, physician assistant, or APRN operating within the supervisor's scope of practice and all statutes and regulations pertaining to the supervisor's license. May be currently allowable or require statute or regulation change to clarify necessary training and education.

**Green:** List of procedures and modalities used in esthetics practices

**Purple:** Examples of brand names, web site links, and other terms and descriptions to help identify and define what is meant by the procedure. This list is not exhaustive.

**Orange:** Description of FDA classification and federal regulatory oversight.

**Blue:** Esthetics Council recommendation whether to allow these procedures under an existing Alaska esthetician license (350 hours of training and independent practice) or whether additional training and education (i.e. statute or regulation change) or medical supervision is needed.

<sup>\*</sup> NOTE: The Esthetics Council recommends the current esthetician license requirements be increased to 600 hours to ensure training on a wide range of basic modalities for which they are licensed.

Procedure  Examples of Common Brand Names, links to web sites  This is a very limited list can be expanded. Most modalities are tied to a product line as well.	Procedure	FDA Designation (Class 1 or 2: Should not fall within Class III, 3A, 3B, or IV Radiation Emitting Devices designation)	FDA Regulation Device required to be registered under 201(h) of the FD&C Act? Product regulated as a cosmetic by FDA?	Safe to allow under existing esthetician license?  • 350 hours training  • Curriculum in 12 AAC 09.163  • NIC esthetician test	If not generally safe under existing esthetician requirements, what is minimum recommended amount and type of training? Should this require supervision by a medical director?
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Ultrasonic devices     Epidermis Impact-Superficial	www.universalcompanies.com www.biotherapeutic.com	Ultrasonic spatula emits high-frequency sound waves, typically at a rate of 20,000 to 30,000 vibrations per second (Hz). Intended outcome: cleansing and exfoliation.	Class I	Yes	Yes	N/A
2. Oxygen Concentrator devices Epidermis Impact- Superficial		Deliver atmospheric concentrated oxygen to the skin to boost circulation, promote healing, and enhance the glow. Intended outcome: Brighter, revitalized skin with improved oxygenation.	Class I  Does not include hyperbaric chamber		Yes	N/A
3. Electrotherapy devices (galvanic current, High Frequency)  Epidermis Impact-Superficial	www.universalcompanies.com www.silhouettone.com www.equipro.com www.massagewarehouse.com	Low-voltage direct current or alternating current (High Frequency) to enhance product penetration, stimulate skin, disinfect, and improve tone. Intended outcome: Improved skin hydration, enhanced product absorption.	Class 1	Yes	Yes	N/A
4. Mechanical brush devices  Epidermis Impact-Superficial	www.universalcompanies.com www.massagewarehouse.com www.zemits.com	Rotary or oscillating brushes for deep cleansing and exfoliation. Intended outcome: Deeply cleansed skin, reduced clogged pores.	Class I- generally unregistered		Yes	N/A
5. Vacuum spray devices	www.universalcompanies.com www.massagewarehouse.com www.zemits.com	Uses suction to clean pores and remove impurities, often	Class I- generally unregistered		Yes	N/A

Epidermis Impact-		combined with a spray				
Superficial		mist to hydrate.				
Capomolat		Intended outcome:				
		Cleansed, refreshed				
		skin.				
6. Steamers	Varies	Generates steam to	Class 1-		Yes	N/A
6. Steamers	www.universalcompanies.com				res	IN/A
Fortal constitution and	www.massagewarehouse.com	open pores and hydrate	generally			
Epidermis Impact-	www.zemits.com	the skin. Intended	unregistered			
Superficial		outcome: Loosening of				
		debris in pores,				
		enhanced product				
		absorption.				
7. LED (light	www.lightstim.com	Emits specific	Class 2	Yes	Yes	N/A
emitting diode)	www.celluma.com	wavelengths of light to				
devices.	www.cettama.com	target acne, reduce				
		inflammation, and				
Epidermis Impact-		stimulate collagen.				
Superficial/Light		Intended outcome:				
		Acne reduction, anti-				
		aging, and skin				
		rejuvenation.				
8. Microcurrent	www.biotherapeutic.com	Low-level electrical	Class 1 or	Yes	Yes	N/A
devices	www.neurotris.com	currents stimulate	Class 2			
	www.silhouettone.com	facial skin, improve	based on			
Epidermis Impact-		circulation and	intended use-			
Superficial		firmness. No direct	direct muscle			
		muscle stimulation	stimulation			
		(visible contractions)	Class 2.			
		Intended outcome:				
		Lifted, more toned				
		facial appearance.				
9.	www.diamondglow.com	Mechanically exfoliates	Class 1	Yes	Yes	N/A
Microdermabrasion	www.hydrafacial.com	the skin using crystals				
devices, including	www.silhouettone.com	or diamond tips, often				
hydradermabrasion	www.equipro.com	with suction. Intended				
devices.		outcome: Smoother				
4341000.		skin texture, improved				
Epidermis Impact-		clarity, and reduced fine				
Superficial		=				
Supernolat		lines.				

10. Skin analysis	Wood's lamp Magnifying Lamp	Uses UV light to	Class 1		Yes	N/A
equipment	i lagiliyilig Lamp	examine skin conditions				
		like pigmentation,				
Epidermis Impact-		hydration, and bacteria.				
None		Mag Lamp uses				
		different levels of				
		magnification with a				
		light source. Intended				
		outcome: Accurate skin				
		assessment for				
		customized treatments.				
11. Thalassotherapy	www.thalgo.com	Uses seawater and	No		Yes	N/A
	www.elemis.com	marine products for	Classification			
Epidermis Impact-	www.massagewarehouse.com www.universalcompanies.com	detoxification and				
Superficial	www.umversatcompanies.com	rejuvenation in body	MOCRA			
		treatments or facials.	registration			
		Intended outcome:				
		Hydration, skin				
		nourishment, and				
		relaxation.				
12. Thermotherapy		Heat application to	Class 1	Yes	Yes	N/A
(application of		improve blood				
heat), manually		circulation and relax				
applied or with the		muscles.				
use of devices.		Intended outcome:				
		Improved skin tone,				
Epidermis Impact-		relaxation, enhanced				
Superficial		healing.				
13. Vitamin-based	Same as above	Vitamins like vitamin C	MOCRA		Yes for	N/A
acids		and retinoic acid are	Registration		light/superficial	1771
doido		applied for antioxidant	Required		peels but	
Epidermis Impact-		benefits and skin	rioquirou		should require	
Superficial at lower		rejuvenation. Intended			manufacturer	
concentrations		outcome: Brightened			training	
Solioontiations		skin tone, reduced			i dililili	
		wrinkles, and sun				
		damage.				
14 Superficial and	Varies-common vendors.	-	MOCRA		Yes for	Recommend
14. Superficial and	www.circadia.com	Chemical agents				
light chemical	www.dermastart.com	applied to exfoliate the	registration		light/superficial	performance of
exfoliation including	www.linderhealth.com	outer skin layers.			peels but	

but not limited to; alpha hydroxy acids, beta hydroxy acids, modified Jessner solutions, and trichloroacetic acid less than 20% Epidermis Impact- Superficial at lower concentrations	https://www.dannemking.com www.osmosis.com www.skinscript.com www.haleandhush.com www.pcaskin.com	Chemical peels available to estheticians are light & superficial light depth. Intended outcome: Smoother, more radiant skin, treatment of acne or hyperpigmentation	required for products		should require manufacturer training	Modified Jessners and TCA only by an Advanced/Master Esthetician (900- 1200hr)
15. Low-Level	www.environ.com	Uses low-intensity	Class I or II	Yes	No	Recommend
Ultrasound devices	www.zemits.com	ultrasonic waves	based on			performance only
(Sonophoresis)	www.massagewarehouse.com	typically below 3 MHz,	intended use			by an
		which target more				Advanced/Master
Epidermis Impact-		superficial layers of the				Esthetician (900-
Superficial		skin. Intended				1200hr)
		outcome:				
		Skin texture				
		improvement, product				
		penetration, and superficial treatments				
		like cellulite				
		appearance reduction.				
16. HIFU (High		Utilizes high-intensity	Class II	Yes	No	Recommend
Intensity Focused		ultrasound waves,				performance only
Ultrasound)		delivering focused				by an
		energy to precise				Advanced/Master
Epidermis Impact-		depths.				Esthetician (900-
Superficial-Medium		Intended outcome: skin				1200hr)
Dermis Impact		tightening, non-surgical				
Deep		facelifts.				
		1.5 mm: This shallow				
		depth targets				
		3.0 mm: This depth				
		targets the deeper				
		dermal layer.				
		4.5 mm: This depth				
		reaches the SMAS layer				
		(Superficial Muscular				
		Aponeurotic System)				

17. Low-Level Radio Frequency devices Epidermis Impact- Superficial	www.nuface.com www.zemits.com	Operates at lower power and frequency compared to traditional RF devices. The energy delivered is less intense, so it targets the upper skin layers. Intended outcome: Used for superficial skin treatments like mild skin tightening, improving circulation, and stimulating collagen production without deep tissue penetration.	Class II (includes OTC)	Yes	No	Recommend performance only by an Advanced/Master Esthetician (900- 1200hr)
18. Radio Frequency devices  Epidermis Impact- Medium Dermis Impact- Deep	www.candelamedical.com www.morpheous8.com	Operates at higher power and frequency, delivering more energy to the skin. RF devices typically heat tissues more deeply, stimulating collagen in the deeper dermis and subcutaneous layers. Intended Outcome:  Designed for deeper skin tightening, lifting, and more intensive collagen remodeling.	Class 2 or Class 3 based on intended use	Yes	No	Recommend performance at Class 2 only by an Advanced/Master Esthetician (900- 1200hr)  Performance at Class 3 only by a trained physician, physician assistant, or APRN.
19. Cryotherapy (application of cold), manually applied or with the use of devices.  Epidermis Impact- Superficial	Same as above www.artemis.com www.zemits.com www.universalcompanies.com www.thalgo.com  Superficial body treatments included.	Does not employ nitrogen spray; is not cryolipolysis or cryosurgery. Cold application to reduce redness, improve circulation, and tighten skin.	Class 1  MOCRA registration for products	Yes	Yes, but only manual application or cold tools	Recommend performance using a device only by an Advanced/Master Esthetician (900- 1200hr)

Not Lipolysis (Coolsculpting)		Intended outcome: Reduced redness, firmer skin.				
20. Hydrotherapy  Epidermis Impact- Superficial	www.thalgo.com www.massagewarehouse.com	Water-based treatments for relaxation, detoxification, and skin hydration including Vichy shower, Scotch hose & hydrotub. Intended outcome: Relaxation, improved circulation, and	Class 1 (hydrotherapy tubs, showers) No classification for products.	Yes	Yes, not including Vichy shower or scotch hose.	Recommend performance of Vichy shower and Scotch hose only by an Advanced/Master Esthetician (900- 1200hr)
21. Cellulite appearance and contouring treatments  Epidermis Impact- Superficial Dermis Impact- SMAS or Deeper depending on device	Same as above www.artemis.com www.zemits.com Body treatments including wraps.	hydrated skin.  Non-invasive treatments targeting cellulite with mechanical stimulation, manual body treatments or energy-based devices. Intended outcome: Smoother skin texture, reduced appearance of cellulite.	Class 1 or Class 2 depending on modality used.  MOCRA registration for body treatment products.	Yes	Yes, only superficial	Recommend performance affecting below the epidermis only by an Advanced/Master Esthetician (900- 1200hr)
22. Dermaplaning devices  Epidermis Impact-Superficial	www.dermaplane.pro	Manual or mechanical exfoliation that removes the top layer of dead skin and fine hair. Intended outcome: Smooth skin texture and enhanced product absorption.	Class 1	Yes	No	Recommend performance only by an Advanced/Master Esthetician (900- 1200hr)
23. Mechanical body stimulation  Epidermis Impact-Superficial/Medium	G8, Endermologie www.universalcompanies.com www.massagewarehouse.com	Devices that use rolling, kneading, or suction to stimulate circulation and reduce cellulite. Intended outcome: Smoother skin	Class 1	Yes	No	Recommend performance only by an Advanced/Master Esthetician (900- 1200hr)

		appearance, reduced cellulite.				
24. Collagen induction device (microneedling) *Includes microchanneling or nanostamp not OTC devices	www.dermapen.com https://360aestheticdevices.com www.candelamedical.com	Uses tiny needles to create micro-injuries, stimulating collagen production. Ranges .25-2.0 mm. Intended outcome: Improved skin texture, reduced wrinkles, acne	Class 2	Yes	No	Recommend performance of up to .1mm only by an Advanced/Master Esthetician (900- 1200hr)
Epidermis Impact at or below 1mm- Superficial Dermis Impact- 1.5mm-2.5mm		scars.				Deeper penetration should require medical supervision

#### **Resources:**

https://www.commercealaskagov/web/Portals/5/pub/MED\_Guide\_Dermatologicalpdf
https://www.commercealaskagov/web/Portals/5/pub/MED\_Guide\_Lasers\_Laser\_Surgerypdf
https://www.commercealaskagov/web/Portals/5/pub/MED\_Guide\_Delegating\_to\_Unlicensed\_Assistantspdf
https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofNursing/AdvisoryOpinions.aspx

https://www.commercealaskagov/web/Portals/5/pub/MedicalStatutespdf https://www.commercealaskagov/web/Portals/5/pub/NursingStatutespdf https://www.commercealaskagov/web/Portals/5/pub/BAH\_Stats\_Regspdf

# Draft language suggested for Board of Barbers and Hairdressers regulation definition of "appliances" available for use as a licensed esthetician without medical supervision with only 350 hours of training as described above:

The use of esthetic devices, or combinations of devices that stimulate natural physiological processes intended to improve skin appearance and health, devices should meet the following criteria: Do not directly ablate or destroy live tissue, or involve incision into skin beyond the epidermis. Devices must operate within manufacturer guidelines, and FDA registration if required by 21 U.S. Code § 321 of the Federal Food, Drug, and Cosmetic (FD&C) Act. These devices should not fall within Class III, 3A, 3B, or IV Radiation Emitting Devices designation.

### **FDA Classification**

FDA Device Classification Database: <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm</a>

Devices used in cosmetic and therapeutic treatments must undergo appropriate FDA review based on their **classification** under the FD&C Act. Devices are classified into three categories based on their risk level:

- Class I Devices (Low-Risk): These devices are considered to have the lowest risk to users. Examples include simple cosmetic tools like mechanical exfoliation brushes or handheld LED devices. Class I devices are generally exempt from premarket notification (510(k)), although manufacturers are still required to register their facility and list their devices with the FDA.
- Class II Devices (Moderate-Risk): Devices that pose moderate risk and require special controls to ensure safety and effectiveness. Examples include; radiofrequency (RF) devices for skin rejuvenation, ultrasonic disinfectant devices, certain paraffin dips, microneedling, and LED devices. Class II devices must undergo the 510(k) premarket clearance process, where manufacturers must demonstrate that the device is substantially equivalent to a legally marketed device.
- Class III Devices (High-Risk): These devices present the highest risk to patients and typically require premarket approval (PMA) from the FDA. Devices in this category are often those intended for critical functions, such as lasers for surgical use or invasive treatments. High-Intensity Focused Ultrasound (HIFU) for deep skin tightening may fall under this classification.

#### Labeling

• The FDA distinguishes between **Over the Counter (OTC)** and **Prescriptive (Prescription)** devices based on their intended use, safety, and the necessity of professional supervision. This designation pertains to **LABELING** requirements only. The **FDA does not designate who is qualified to use such devices, this is a STATE regulatory issue.** 

## Key Points about Cosmetic Devices:

- Cosmetic Claims: Devices used for purely cosmetic purposes can make cosmetic claims, but they cannot make medical claims (such as treating wrinkles, acne, or skin diseases) without being regulated as medical devices. Examples of cosmetic claims would be "improves skin appearance" or "hydrates the skin" without implying treatment of any medical condition.
- No "Cosmetic Device" Category: The FDA does not have a special category for "cosmetic devices." If a device interacts with the skin and claims to change its structure, function, or treat a condition (such as wrinkles or acne), it is classified as a medical device, even if the primary purpose seems cosmetic.
- Pre-Amendment Devices: example: Galvanic Current Devices & Tesla High Frequency (Electrotherapy Category)
  - o Devices that were legally marketed in the U.S. before **May 28, 1976**, are known as **pre-amendment devices**.
  - These devices were grandfathered under the Medical Device Amendments of 1976, meaning that they could continue to be marketed without going through the new premarket approval process that was introduced after the amendments.
  - o Pre-amendment devices still need to comply with certain FDA requirements, including **registration** with the FDA and compliance with applicable regulations such as **labeling** and **Good Manufacturing Practices (GMPs)**.

## MOCRA (Modernization of Cosmetics Regulation Act)

MoCRA Registration info: https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products

While **MOCRA** directly pertains to **cosmetic products** (like creams, lotions, and makeup), it does not apply to **devices**. However, it is essential for device manufacturers who also create cosmetic products to understand the new requirements under MOCRA:

- Mandatory Facility Registration: Cosmetic product manufacturers must now register their facilities with the FDA. Device manufacturers should ensure that any cosmetic products used with their devices (e.g., serums for micro-needling or topical treatments for ultrasonic devices) comply with this requirement.
- Adverse Event Reporting: MOCRA requires reporting of serious adverse events related to cosmetic products, which extends to cosmetic treatments used in conjunction with FDA-registered devices.
- Good Manufacturing Practices (GMPs): While devices are already subject to GMPs, MOCRA introduces specific GMP requirements for cosmetic products, which may influence manufacturers of dual-use products. GMP cosmetic manufacturing guidelines are scheduled for 2025.
- **Product Registration**: Brands and manufacturers that sell directly to the public must register their products with the FDA, this includes labeling requirements that include "professional use" designation on products. Fragrance allergens are included, and guidance is further scheduled in the FDA rulemaking process through 2025.