

DEPARTMENT OF HEALTH

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Body Art Procedures, N.J.A.C. 8:27
Rule Interpretation and Policy Statement: Microdermal Anchors

See relevant definitions: "Implant," "Instrument," "Jewelry" and "Single use."

This Rule Interpretation and Policy Statement document was developed as a response to questions concerning the acceptability of microdermal anchors (otherwise known as surface anchors, microdermals, microdermal implants, microdermal piercings etc.) – small transdermal devices inserted by single point piercings – for use in New Jersey body art establishments. The Public Health Food and Protection Program (PHFPP) has determined that microdermal anchors do not differ significantly from traditional surface piercings and that the current Body Art Procedures rules do not exclude their use.

Microdermal anchors, although implanted in the skin, should be distinguished from subdermal implants and larger transdermal implants which remain prohibited. Microdermal anchors can be simply inserted and removed by experienced practitioners. Healing and complications following microdermal anchoring appear to be comparable to other types of piercings.

PHFPP is stipulating certain restrictions and guidelines for their use. In addition, approved practitioners should follow current industry best practices, including the recommendations of device manufacturers and industry associations. For example, the position of the Association of Professional Piercers (APP) is that microdermal anchors are acceptable body piercings and that "when properly performed by a skilled practitioner, surface anchor piercing is no more risky than an ordinary body piercing and takes no longer to perform or to heal."

As the main entity with responsibility for implementation and enforcement of the Body Art Procedures rules, local health departments may choose to adhere to a strict interpretation of the "implant" definition found in the current rules, and prohibit the use of microdermals. However, the New Jersey Department of Health, PHFPP, through this document, approves of the use of microdermals in body art establishments. This document may be revised as needed, based on new evidence, concerning the use of microdermal anchors.

The following restrictions and guidelines shall be followed when body piercing practitioners in licensed/permitted body art establishments are approved to perform microdermal anchoring:

- The approved body piercer shall have a minimum one year of experience as a practitioner, shall provide documentation of education in microdermal anchoring, and shall closely follow all relevant standards, specified in the Body Art Procedures rules.
- The approved body piercer's professional liability insurance shall specifically include a "surface anchoring endorsement."
- Written procedures for the insertion and removal of anchors and the changing
 of threaded end ornaments shall be developed and maintained at the body art
 establishment for reference. Consumers shall be strongly advised to use an
 approved body piercer for any alterations to microdermal anchors.
- Anchor (foot or base) devices must be made only of ASTM/ISO certified materials with biocompatibilities equivalent to medical implants, such as titanium (ASTM F-136) and surgical grade stainless steel (ASTM F-138).
 8:27 definition, "Jewelry" means any personal ornament inserted into a newly pierced area, and may be made of surgical implant grade stainless steel, solid 14 karat or 18 karat white or yellow gold, niobium, titanium, platinum, glass, or a dense, low-porosity plastic.
- Anchors/jewelry shall have no exposed threads.
- Anchors shall not exceed sizes typical for microdermal anchors as currently known and understood, i.e., no greater than 8mm.
- Piercing instruments shall be sized no greater than needed to facilitate anchor placement.
- Proper skin preparation and aftercare shall be emphasized. Issues such as snagging and migration of jewelry shall be reviewed with the consumer.
- Consumer consent forms shall clearly specify the procedure as microdermal or surface anchoring and a copy of the consent form shall be provided too the consumer, following a thorough review of expected results and possible complications.
- The body art establishment shall maintain a log "in accordance with the provisions of N.J.A.C. 8:27-4.6", Operator Reporting Requirements. The operator shall notify the local health authority and the PHFPP within 24 hours of any infection or injury requiring a medical referral.

Dermal (biopsy) punch, scalpel, and hemostat use

Dermal punches, scalpels and hemostats are medical devices classified by the Food and Drug Administration as manual surgical instruments for general use (Class 1, 510K exempt). The PHFPP is not presently aware of any FDA restriction that would prevent their use for non-medical/surgical procedures, such as microdermal anchoring. Similarly, the PHFPP is not presently aware of any New Jersey State Board of Medical Examiners (BME) restriction that would prevent their use by body piercers. However, body piercing practitioners should consult their own sources and keep current in this regard. If used, dermal punches and scalpels shall be **single use only**; that is, these devices must be handled like piercing needles and must be discarded after each piercing procedure, into sharps containers designated for regulated medical waste. Hemostats or other similar devices that penetrate skin tissue during anchor placement or removal shall be **sterile**, and if reused, shall be thoroughly cleaned and re-sterilized prior to next use.

Please direct questions or comments to:

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