

New York State Department of Taxation and Finance  
**Office of Counsel**  
**Advisory Opinion Unit**

TSB-A-09(47)S  
Sales Tax  
October 14, 2009

STATE OF NEW YORK  
COMMISSIONER OF TAXATION AND FINANCE

ADVISORY OPINION

PETITION NO. S081231B

Petitioner [REDACTED], asks whether its purchases of dermal fillers used by Petitioner in the performance of surgical procedures are subject to sales tax.

We conclude that dermal fillers (“injectable implants”) are supplies used in the performance of medical surgery procedures and are thus subject to sales tax when purchased for use by persons performing medical services for compensation.

**Facts**

Petitioner operates a licensed medical practice performing plastic and reconstructive surgery.

Due to the effects of disease, injury or age, the skin and related soft tissue of individuals suffer and degenerate. Pursuant to FDA approved procedures, dermal filler is injected into the patient to replace, augment, or otherwise restore the function of various types of soft tissue.

The injectable dermal fillers/ implants used by Petitioner are Radiesse© (calcium hydroxylapatite suspended in a sodium carboxymethylaluclose gel carrier) and Restylane© (a hyaluronic acid gel). These products come ready-mixed and prepared in sterile, single-use syringes. They may only be purchased by licensed medical practices and administered by physicians.

In the United States, Radiesse© is FDA approved for the correction of moderate to severe facial folds, such as nasolabial folds (the wrinkle lines from the sides of the nose to the corners of the mouth), and for the correction of the signs of facial lipoatrophy (the technical term for the loss of subcutaneous fat in the face) in HIV patients. There are also FDA clearances for use of Radiesse© in respect of oral/maxillofacial defects, vocal fold insufficiency and radiographic tissue marking. The FDA order (submitted as *Exhibit B* of the Petition) approving the use of Radiesse© in facial lipoatrophy refers to Radiesse© as a device.

Radiesse© is described as being suitable for the treatment of facial lines and wrinkles around the nose and mouth. These lines typically follow one of two patterns, running from the nose to the corners of the upper lip (nasolabial folds) or pointing down from the corners of the mouth to the chin (marionette lines). Smile lines are the common facial lines and wrinkles that appear on the cheeks. *See* [radiesseusa.com](http://radiesseusa.com) website.

Facial lipoatrophy can result in sunken cheeks, hollow eyes, and facial indentations. Radiesse© dermal filler is a treatment option for patients with HIV-associated facial lipoatrophy.

The FDA also permits Radiesse© to be used:

- to fill and or augment periodontal defects, ridge augmentation, extraction sites, craniofacial augmentations (craniofacial defects caused by trauma or birth defects), sinus lifts and cystic defects (oral/maxillofacial defects)

- to assist in the correction of bowing or paralysis of the vocal cords by support via injection of the vocal fold and its supporting structure (vocal fold augmentation); and
- to mark the precise location of internal sites for surgery and therapeutic treatments (radiographic tissue marking)

Restylane© is also an FDA approved dermal filler used for restoring volume and fullness to the skin in the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.

Both Restylane© and Radiesse© remain in the patient's body temporarily as a separate and identifiable material. Petitioner states, that while in the body, it restores the functioning of an organ (skin and related tissue) that is otherwise permanently inoperative or malfunctioning. Over time, the body will absorb the injected material. The absorption process for Restylane© is approximately six months (or longer) and for Radiesse © one year (or longer). After absorption, the skin and related tissue return to their previous state until the procedure is repeated and new material is injected into the patient.

### **Analysis**

The Tax Law provides exemptions from sales and use tax for drugs and medicines intended for use in the cure, mitigation, treatment or prevention of illness or disease in humans; and for medical equipment (including component parts thereof) and supplies required for use in the cure, mitigation, treatment or prevention of illness or disease, or to correct or alleviate physical incapacity. However, the exemption is not provided for medical equipment and supplies purchased at retail for use in providing medical and similar services for compensation or for cosmetic products notwithstanding the presence of medicinal ingredients in the cosmetic product. (*See Tax Law Section 1115(a)(3).*)

The Tax Law also provides an exemption for prosthetic aids, artificial devices and component parts thereof purchased to correct or alleviate physical incapacity in humans. (*See Tax Law Section 1115(a)(4).*) The Sales and Use Tax Regulations describe prosthetic aids and artificial devices, and component parts thereof, purchased to correct or alleviate physical incapacity in human beings as property that either completely or partially replaces a missing body part or the function of a permanently inoperative or permanently malfunctioning body part and that is primarily and customarily used for such purposes. Property that is generally useful in the absence of illness, injury or physical incapacity does not qualify for the prosthetic aid, artificial device, etc. exemption. (*See Regulation Section 528.5*)

The Radiesse and Restylane products are not exempt as prosthetic aids or artificial devices under Tax Law Section 1115(a)(4). The fact that these dermal fillers are absorbed by the body rather than becoming a replacement for a malfunctioning body part indicates that they are not prosthetic devices. (*See Alcon Surgical Inc., Adv Op Comm Tx & Fin, May 27,1992 TSB-A-92(43)S.*) Moreover, these products are not exempt drugs or medicines pursuant to Tax Law section 1115(a)(3).

These products, in view of all their approved uses (cosmetic procedures, surgical marker, defect augmentations, etc.), are medical/surgical supply items that can be used to correct or alleviate physical incapacity, similar to sutures (*Alcon Laboratories, Inc., Adv Op Comm Tx & Fin, August 2,1991, TSB-A-91(54)S*), ophthalmic shields (*Alcan Surgical Inc., supra*), synthetic bone void fillers (*Orthovita, Inc. Adv Op Comm Tx & Fin, June 25, 2002,TSB-A-02(14)S*), absorbable tissue regeneration device (*John O. Butler Company, Adv Op Comm Tx & Fin, November 4,1992, TSB-A-92(77)S*) and other items used and consumed by medical practitioners in performing medical procedures. *See also Dental Society of the State of New York v NYS Tax Commission, 110 A.D. 2d 988 (1985)* which held that cavity filling materials implanted

in patient's teeth were taxable supply items. As medical supply items, these products are subject to sales tax when purchased for use in the performance of medical and similar services for compensation.

DATED: October 14, 2009

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Jonathan Pessen  
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NOTE: An Advisory Opinion is issued at the request of a person or entity. It is limited to the facts set forth therein and is binding on the Department only with respect to the person or entity to whom it is issued and only if the person or entity fully and accurately describes all relevant facts. An Advisory Opinion is based on the law, regulations, and Department policies in effect as of the date the Opinion is issued or for the specific time period at issue in the Opinion.