PRODUCT DESCRIPTION

TruPigment™ is a non-cultured epidermal-cell suspension (NCES) prepared from a split thickness skin sample, collected aseptically, from the same individual that will receive it for transplantation (autologous). TruPigment™ is processed and packaged using aseptic techniques, in a clean, controlled environment in compliance with FDA requirements for current Good Tissue Practices (cGTP). TruPigment™ is treated with antibiotics as a decontamination step. Solutions that may contain porcine-derived enzymes, bovine lactose-based products, and soy-based products are introduced during the processing of the product. TruPigment™ is washed to remove antibiotics and processing solutions, however trace amounts may remain. Extraneous tissue has been removed. To maintain cell viability, TruPigment™ is not terminally sterilized.

TruPigment™ is shipped following a test to confirm the absence of endotoxin. Rapid tests for microbial contamination are initiated before release. Mycoplasma results are available by the following day. Final (7-day incubation) test results for absence of bacteria, fungi, yeast, and mold are completed after the time of cell transplantation. Individuals and/or their skin samples (autologous) are not routinely tested for transmissible infectious agents. Despite processing techniques designed to reduce or eliminate contaminants, TruPigment™ is supplied non-sterile and may contain pathogens.

INDICATION FOR USE

TruPigment™ is intended for autologous transplantation to the same individual whose skin sample was collected and processed into the NCES. TruPigment™ is intended for homologous use, replacing missing melanocytes and other epidermal cells to advance restoration of skin pigmentation, a basic protective function of the epidermis. NCES’s are used, in combination with other treatments such as dermabrasion and laser skin resurfacing, to advance the replacement and repair of lost skin color in a variety of depigmentation applications. TruPigment™ should only be used as it is intended by qualified health care professionals.

CONTRAINDICATIONS

- Indications of compromised wound healing such as significant bleeding disorders, diabetic, smoker, cardiac insufficiency, use of blood thinners.
- Blood-borne infections (e.g. Positive serology of herpes, HIV, hepatitis B and C)
- Any history of keloidal scarring or koebnerization
- Functional impairment, pain or infection in treatment area
- Immunocompromised conditions
- Pregnant or lactating women
- Hypersensitivity or allergy to one or more processing solutions of TruPigment™ (porcine-derived products, bovine lactose products, soy-based products, antibiotics: Gentamicin, Amphotericin B).
- Hypersensitivity or allergy to local anesthesia.
- Additional contraindications to surgery

WARNINGS

- TruPigment™ is for AUTOLOGOUS USE ONLY.
- Do not sterilize.
- Do Not Re-Use, intended for single application only.
- Do not use if the container or its seal is damaged, leaking, or not intact.
- Do not use if the container label or identifying code is severely damaged, unreadable or missing.
- Do not use if there is concern of contamination of the materials.
- Do not use if the container has been allowed to freeze.
- Do not use If the container has been stored at temperatures that exceed 10°C (50°F)
- Do not use If Patient ID on the package does not match ID of patient being treated.
- Do not use if the “Do Not Use After” Date shown on the container label has passed.

PRECAUTIONS

- Aseptic technique is mandatory when using TruPigment™. Follow appropriate personal protective equipment (PPE) guidelines for de-epithelization techniques (such as mask and protective eyewear) in accordance with local, state and federal requirements.
• Handle TruPigment™ applicator with care so as not to dislodge cell suspension.
• Dispose of excess or unused tissue and all packaging that has been in contact with the tissue in accordance with recognized procedures for discarding regulated medical waste materials in accordance with local, state and federal requirements.

ADVERSE EFFECTS/REACTIONS
As with any de-epithelization procedure (used to prepare the recipient site for TruPigment™) there is potential for adverse effects such as pain, erythema, post-inflammatory discoloration (hypopigmentation or hyperpigmentation), koebnerization or slight textural change and infection at the site of grafting. Adverse reactions reasonably attributable to TruPigment™ must be promptly reported to TeVido BioDevices, Inc.

DONOR TESTING
US federal regulations do not require testing of autologous donors for transmissible agents.

STORAGE, PACKAGING & LABELING
• TruPigment™ consists of viable, autologous cells packaged and labeled for use within specified time limits.
• TruPigment™ is aseptically packaged in 1 ml applicator(s) that are double bagged, with the label on the inner bag, and packed into a carton. The carton is provided in a shipping package.
• The product tradename, short description, patient name, patient medical record number, Do Not Use After Date, TeVido Lot Code, volume, amount, and additional information are provided with the shipping package.
• TruPigment™ should be refrigerated for short-term storage before application, do not freeze.

APPLICATION/ADMINISTRATION
Professional judgment based on clinical evaluation determines the skin sample size that is provided, by the health care professional, for processing into TruPigment™.

The recipient site is prepared for cell transplantation by de-epithelization. A number of techniques may be used to prepare the site; selection is based on clinical judgment and the relevant guidelines should be followed. The aim of recipient site preparation is to remove the epidermis to the level of the Dermal-Epidermal Junction, allowing transplanted melanocytes to access structures necessary for adherence and nutrition. After recipient-site preparation, TruPigment™ is uniformly applied to the de-epithelialized area using the 1 ml applicator. The site is dressed per standard wound healing guidelines, with a non-adherent, non-absorbent material as the first layer to prevent trauma to the cells.

See Instructions for Use (IFU). Failure to use TruPigment™ per IFU may lead to suboptimal outcomes, product failure, and/or patient harm.

REGULATORY CLASSIFICATION
TeVido BioDevices is registered with the US Food and Drug Administration (FDA) as a human cells, tissues, and cellular and tissue-based product (HCT/P) regulated solely under Section 361 of the Public Health Service Act and the Code of Federal Regulations Title 21, Part 1271.