

IMPORTANT: READ BEFORE USE

Any of the safety issues associated with implanting techniques in radiotherapy, Laboratoires BIOTIC PHOCEA offers a solution to its clients for Roadsafe®. The coloured markers that provide the "product" designed to improve the marking use of these products. Laboratoires BIOTIC PHOCEA may therefore not be held liable for any damage caused by the products as a result of total or partial incompatibilities with the instructions contained in this leaflet. The sole legal responsibility for providing information about the risks is held by the user and is assessed from a radiotherapy marking technique by the professional user.

Presentation, Identification, Conservability and Traceability

Coloured dispersion, intended to make marks for radiotherapy fields by skin implants using a sterile lancet or a tattoo machine and a sterile needle.

The product is provided in sterile packaging designed for single use only. The product is identified by its name, product reference and batch number which must be retained by the practitioner. The composition and presentation comply with Directive 93/42/CEE covering medical devices. The Products belong to the medical device category IIb.

The product must be stored in its original packaging in a dry place at room temperature, away from dust. The Product should not be exposed to light. Do not freeze. The product must be stored in normal environmental and physiological conditions (pressure, temperature, irradiation, electric and magnetic waves, acceleration...). If these conditions are not met, the product must be used.

Warnings: The product is delivered sterile in sealed packaging. The product is designed for single use only. Please check that the packaging has not been damaged before use: if it is damaged in any way, the product must not be used. Do not re-use the product. Do not re-sterilise the product. Check the use-by-date. Do not use the Product if you notice anything unusual about it (abnormal colour or appearance, etc.). Please inform Laboratoires BIOTIC PHOCEA and return the product. Do not alter the Product by addition, mixing with any other product, pigment dispersion, other substance, any irradiation to the original formula, tampered/removed packaging or inappropriate use (relieves the Manufacturer of all liability and/or warranty obligations). If any change is noticed in product performance - provided the guarantee is applicable and proper use has been made of the product - please contact Laboratoires BIOTIC PHOCEA with all relevant documentation so that corrective and preventive actions may be implemented, including Product withdrawal and/or a recall procedure. In compliance with French materiovigilance procedures, if the user notices a difference in Product performance, they must stop using all Products from the same batch or with identical reference numbers and immediately contact Laboratoires BIOTIC PHOCEA.

Indications: The product is intended to be inserted into the dermis or mucous membranes in a sterile manner with the aim of marking irradiation fields in radiotherapy. Not to be used in the eye.

Contra-indications: The product is designed for single use only and must not be re-used. If the Product is re-used it is no longer sterile and may present the risk of infection. Where there is a known illness, the practitioner must seek medical advice before performing any procedure. The product should not be used on infected or diseased skin, (past or present), hypertrophic scars, affected organs close to the skin (eyes) or minors with general ill health. The Product should not be used on minors or pregnant women. Tattoo inks must not be used on allergic patients¹, individuals carrying a medical device (pacemakers, in particular) or persons with blood clotting disorders (platelets, anti-inflammatory drugs...). ^(*) Certain shades may contain traces of chromium and/or nickel

Precautions for use: Only a competent and trained professional may practice radiotherapy marking. In order to prevent the risk of allergic reactions to the specific composition of the Product, BIOTIC PHOCEA Laboratories recommend using a dermal response test (Dermal test²) a month before micropigmentation. Failing this, Laboratoires BIOTIC PHOCEA declines all liability in the event of an allergic reaction. If the test yields a positive response, micropigmentation should not be performed. If the test produces an unclear result, a second test must be carried out. The pigmentation area must be carefully decontaminated. ^(**) Available from Laboratoires Biotic Phocsa

Potential side effects and complications: As with all medical/surgical interventions, side-effects may occur which are not necessarily caused by the Product. Professionals must inform their clients about possible immediate and delayed side-effects:

- Bruising/Haematoma
- Inflammation/ infection (particularly herpes flare-up);
- Allergy/intolerance
- Reactivation of a pre-existent skin disorder
- Visible scar

Any other side-effect of micropigmentation triggered by the product should be reported to Laboratoires BIOTIC PHOCEA.

Contraindications for use: This Product is designed to be inserted into the dermis or mucous membranes in a sterile manner. Results are highly dependent on the skill of the tattoo artist. The type of equipment that is used and the infection. The technical procedures are necessarily under the responsibility of the professional having received specific training to mark the irradiation fields. It is the professional's responsibility to determine the appropriate procedures based on their experience, personal judgment and standard techniques. The professional must comply with contraindications. Aseptic technique should be used when handling the Product, and skin and mucous membranes must be decontaminated. Marking should only be carried out using equipment that complies with regulatory requirements. The professional carrying out the marking must ensure Product traceability (notably the batch number). Marking must be carried out using aseptic technique and sterile equipment.

As the pigments are held in suspension in medication is a normal occurrence; it is important to mix the Product well prior to use. Any remaining product after each session must not be reused. It must be considered as contaminated medical waste and disposed of as such. The professional who has carried out the marking must keep the batch number of the product used and give the patient the duly completed Implant card.

Use-by date: The use-by date is the date up until which the Product may be used with the guarantee that it is aseptic.

Warranty limitations: The Laboratoires BIOTIC PHOCEA warranty covers the manufacturing process used for the product and its compliance with French legislation. Once product ownership has been transferred, Laboratoires BIOTIC PHOCEA is no longer responsible for the conditions of storage and the proper use of the product, and may not be held liable for the effect and/or consequences of the inappropriate use of the product, including non-compliance with the directions for use in the user notice and/or specific requirements imposed by the legislation of the country in which the Products are used. Laboratoires BIOTIC PHOCEA may not be held liable for medical hazards if the operator does not have the required qualifications for carrying out marking. The warranty expressly excludes claims pertaining to unsatisfactory cosmetic results. Colour consistency and stability over time depend on a number of individual factors which are unpredictable, and by which the manufacturer may not be held responsible. Colour inconsistency, colour shift and loss of colour of the Product over time is normal, and depends on the type of pigment that is used, tattooing technique, individual response and external factors, such as overexposure to sunlight. Compatibility with pigments, pre-dispensed coloured inks and suspension other than those manufactured by Laboratoires BIOTIC PHOCEA, are not covered by the warranty.

Symbol	Meaning	Symbol	Meaning
	Do not sterilize		Do not reuse
	Expiry date		Batch code
	CE Marking in accordance with Directive 93/42/CEE		Name and address of the manufacturer
	Date of manufacture		Sterilization method using irradiation
	Commercial name of the product		Refer to the user manual
	Warning: see instruction leaflet		Keep away from sunlight
	Keep dry		Temperature limit