Panthera Dental Inc.
9105 rue John-Simons
Quebec City, Quebec
Canada G2B 0S6
Tel. +1 855 233-0388

EC REP Obelis s.a.
Bd Brand Whitlock 30,
B-1200 Brussels, Belgium
Tél. +(32) 2732-59-54
Fax : +(32) 2732.60.03
E-mail : mail@obelis.net

Panthera Dental CAD/CAM Subperiosteal Implant™
Instructions for use – Dental Practitioner Guide

This notice is not intended to replace or supersede sound medical judgment, dental practitioner's experience or training. Panthera Dental does not provide medical advice.

Description: The CAD/CAM Subperiosteal ImplantTM is indicated for use in surgical and restorative applications for placement on the bone of the mandible to provide anchoring or support for prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function.

Materials: The CAD/CAM Subperiosteal Implant is made of titanium Ti6Al4V ELI, grade 23, certified ASTM F136[1].

Packaging content: One (1) CAD/CAM Subperiosteal Implant with healing abutments retained by screws.

Indications for Use: The CAD/CAM Subperiosteal Implant is intended to be used for the lower jaw in patients who are partially edentulous with Kennedy class I, II and III and with bone type of division C-h. The implant is designed for the mandible in situations of severe vertical bone atrophy. It is recommended that the patient have 7 mm of bone or less from the crestal bone level to the inferior alveolar canal.

Contraindications:

The CAD/CAM Subperiosteal Implant is contraindicated for patients:

- Who are active smokers;
- Who are unfit for an oral surgical procedure;
- Who are allergic or hypersensitive to titanium TI6Al-4V and/or stainless steel;
- Who have an inter-arch distance inferior to 8 mm;
- Who have fewer than 6 remaining teeth, precisely from the 33 to the 43.

Attention: To avoid failure, follow all guidelines included with the CAD/CAM Subperiosteal Implant. Non-observance of the indicated limitations of use and surgical protocol may result in failure. A close cooperation between Panthera Dental, the surgeon, the restorative dentist and the dental laboratory is strongly recommended for a successful treatment.

Directions for use: Refer to the Panthera Dental CAD/CAM Subperiosteal Implant Operative and CBCT Scanning protocols #L-014 and #L-015 (at **www.pantheraimplant.com**).

Warning: All surgeons must attend an approval training class to obtain permission to use the Panthera Dental CAD/CAM Subperiosteal Implant. As a unique product, no third party training can replace original and approved training by Panthera Dental.

European, U.S. and Canadian Federal Laws restrict this device to sale by or on the order of a licensed dentist or physician.

Sterilization: The CAD/CAM Subperiosteal Implant is sold NON STERILE. It is the responsibility of the dental practitioner to clean the implant before its use, in conformance with the general dentistry practices. The CAD/CAM Subperiosteal Implant must be sterilized before use with the following validated cycle: Pre-vacuum steam sterilization for wrapped instruments, 4 minutes at 132°C, followed by a drying time of 30 minutes. The validated sterilization process should be performed in a validated sterilizer and the use of it should be in accordance with a recognized sterility assurance standard such as ANSI/AAMI ST79[2].

Maintenance and constant care: Dental practitioners have the responsibility to maintain the functionality and proper storage of the device, while ensuring the safety of the patient with constant care.

Safety, responsibility and warranty: The CAD/CAM Subperiosteal Implant is manufactured in accordance with European, American and Canadian standards for medical devices. No adverse effect is expected or was reported. Physiological and anatomical patient conditions may negatively affect the performance of the device.

Guideline for the patients: Patients are recommended to follow the indications provided by the dental practitioner, go for periodic checks and maintain proper daily dental hygiene.

Technical assistance: Our technicians are available to answer any questions on the use of the Panthera Dental products. You may contact our customer service.

Reference:

1. ASTM F136, Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications.

2. ANSI/AAMI ST79 :2010/A4 :2013, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

	Manufacturer	Rx Only	Prescription only
EC REP	Authorized representative in the European Community		Consult instructions for use
	Do not re-use		Keep dry
NON STERILE	Non-sterile	LOT	Batch code

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