SINUSJET REF SJ1

ENGLISH

Instructions

This document is available at www.synaxial.com or from Synaxial™ by simple request

Carefully read the Directions before using this Synaxial instrument. On their own, the following instructions do not suffice for the performance of transcrestal sinus floor elevation (the intralift procedure). They are intended to ensure proper use of SinusJet™.
A SinusJet™ intralift procedure should be carried out in compliance with generally accepted medical and surgical rules and precautions. Improper use can compromise the success of the procedure and cause irreversible damage. Given that SinusJet™ is used in a context that is out of Synaxial's control, the company denies all liability for any type of harm. All liability is up to the user who must be able to deal with any complication that might arise in the course of surgery or postoperative follow-up. Only a qualified dentist or physician—or someone duly delegated by one—can order or purchase SinusJet™. Only a qualified dentist or physician may use SinusJet™ on a patient.

Description

SinusJet™ is a surgical instrument designed for the intralift procedure, i.e. elevation of the sinus floor with controlled hydraulic pressure at the drill bit. Hydraulic pressure is exerted by isotonic saline solution.
SinusJet™ is designed for simultaneous trephination of the maxillary crest and elevation of the sinus floor, in particular when the crest region between the first premolar and second molar is toothless and atrophic (residual bone tissue of 4-8 mm).
The novel internal irrigation system of SinusJet™ sends isotonic saline solution across the crestal bone during drilling and detaches the Schneiderian membrane before the SinusJet™ enters the sinus cavity.
Its lateral opening allows backflow of the isotonic saline solution, thereby avoiding peaks of pressure in the bone tissue as well as preventing flooding of the sinus and protecting the Schneiderian membrane.

Dimensions

The head of the SinusJet™ has a diameter of 3.3 mm and is 31.5 mm in length.
Laser marks indicate depths of 4 mm, 6 mm and 8 mm.

Materials

SinusJet™ is made of 1.4197 stainless steel with a polyamide grip.

SINUSJET REF SJ1

Indications

Sinus lift by trans-alveolar approach when the height of residual bone is insufficient to allow implantation of a dental implant of sufficient length.

Precautions

The practitioner should check the packaging and expiration date. SinusJet™ should be taken out of the packaging by trained personnel using aseptic technique. SinusJet™ is only compatible with an implantation motor and an internally irrigated contra-angle with its irrigation insert.

Use

The SinusJet™ should be installed in a contra-angle, making sure that the insert is in the right position in its internal slot. The practitioner should make sure that the motor starts at about 1 cc/second and check the saline solution is coming out of the louvres at the head of the instrument. Throughout trephination, fluid should be seen to be flowing back through the lateral SinusJet opening. If irrigation fluid stops flowing at the drill head, stop drilling straight away. Do not start again until flow has resumed and stabilised. If the louvres on the SinusJet are blocked, unblock them or change instrument. Any drop in pressure in the SinusJet can lead to failure. Trephination should proceed at speeds conducive to steady progression. As soon as the sinus floor is breached, stop drilling.

Checking the condition of the Schneiderian membrane by means of a Valsalva manoeuvre

For each well, the intactness of the Schneiderian membrane is checked by means of a Valsalva manoeuvre. Excessive force can tear the Schneiderian membrane so the practitioner should show the patient what to do before the procedure. The result can be interpreted as long as the nasal fossae are free, the sinus meatus is permeable and the sinus is empty. If no air comes out of the well, it can be assumed that the Schneiderian membrane is intact and grafting can go ahead. In contrast, if air escapes through the trephination well, the Schneiderian membrane is damaged and the procedure should be put off: no bone grafting can be undertaken.

OssLift™ grafting. For optimum outcomes, using Synaxial's OssLift™ graft product is strongly recommended.

Tooth extraction can tear membranes so there should be an interval of three months before sinus lift is undertaken.

The contraindications to intralift are exactly the same as those to sinus lift, notably:

Absolute contraindications to intralift: patients with heart disease at risk of infectious endocarditis, patients who recently had an infarction, problems with bone metabolism such as Paget's disease, osteomalacia and osteogenesis imperfecta (Lobstein's disease). Decompensated haematological disorders, drug addiction, alcoholism, smoking, psychosis, psychological and psychiatric problems, functional disorders, xerostomia, immune deficiency, impaired leukocyte function, systemic or local treatments (steroids, anticoagulants, chemotherapy or radiotherapy), patients who are reticent about prostheses on implants, patients of under 18, history of treatment for osteoporosis with C-terminal telopeptide (CTX) < 150 pg/ml. Insufficient bone thickness (less than 2 mm) or no bone.

Relative contraindications: parafunctions, bruxism, occlusal overload, abnormal sinus anatomy, shallow, acutely angled sinus, pregnancy, active gum disease, poor hygiene, infections, buccal inflammation of any aetiology. Abuse of nicotine, alcohol or other drugs (illegal or not).
Local contraindications: insufficient bone thickness or no sinus floor. Residual dental roots. Acutely angled or thin sinus base. Disease that impairs wound healing, bone metabolism or bone regeneration. Diabetes, hypothyroidism (uncompensated or poorly compensated). Medications that compromise tissue healing, e.g. immunosuppressive drugs and chemotherapy. Past radiotherapy of the maxillofacial region. Acute or chronic infection or inflammation of the mouth region. Acute or chronic conditions affecting the sinuses. Blocked or poorly aerated sinus cavities. Blockage of the sinusal meatus or nasal fossae. Poor oral hygiene. Reticence on the part of the patient about orofacial rehabilitation therapy. Poor soft tissue coverage. Incomplete bone development.
Intra-osseous angioma. Cysts on the sinus floor. Intralift is contraindicated after conventional sinus lifting.

Possible health problems during and after surgery
The complications are those possible with any orofacial surgery involving maxillary sinus cavities. These include: nosebleeds, epistaxis, fever, sensitive teeth, bruising, allergy to the materials used. Loss of implants placed in the graft. Graft or implant loss. Inundation of the sinuses with irrigation fluid or blood. Partial or insufficient graft ossification. Migration of the graft or part of it into the sinus cavity. Iatrogenic trauma. Dehiscence of mucosal borders. Aspiration or swallowing of pieces introduced into the mouth. Infectious sinusitis, infection of tissue. Septicaemia. Postoperative infectious blockage of the sinuses. Risk of localised subcutaneous emphysema, possible spreading to the mediastinum and necessitating immediate intensive care. Postoperative pain. Maxillary pain during graft placement. Loss of neighbouring teeth, bone loss of varying extent. Bucco-sinusal fistulae. Migration of the implant into the sinus. Tearing of the Schneiderian membrane during surgery or in the course of a Valsalva manoeuvre.

Patient information
The practitioner should make the patient aware of possible adverse reactions and complications.

Storing the pack
The pack should be handled with care. Keep in a dry place at room temperature protected from draughts, sunlight and dust. The expiration date must be adhered to. If it is passed, do not use the product. Packs should not be open or damaged before use. If there is the least imperfection or you are in any doubt, do not use the product. Only open the pack just before use. The instruments should be handled like any other sterile surgical equipment.

Sterility
SinusJet™ is supplied sterile and ready for single use. It is sterilised by gamma irradiation. SinusJet™ must never be re-sterilised for reuse on another patient. This could endanger the patient's health. The instrument's mechanical properties will no longer be guaranteed and reuse could lead to a poor outcome, incompatible with the desired result and required quality criteria.

SINUSJET REF SJ1

Disposal

After use, this is dental or surgical waste to be disposed of by the practitioner in line with current legislation. In no circumstance can Synaxial™ be held responsible for its disposal.

Availability

Synaxial™ products are not available in all countries

Copyright

This Package Leaflet is the exclusive property of *Synaxial*. Any reproduction, copying or dissemination—by any means and even partial—is forbidden without written permission from *Synaxial™*. The initial text of this Leaflet was written in French. Only the French language version can be used for reference in the event of litigation. This Package Leaflet replaces all previous versions and may be modified at any time without prior notice. It was compiled with every care but, despite our closest attention, it may contain mistakes or omissions. We invite our users to send us comments and contribute to the ongoing improvement of the quality of our products via: info@synaxial.com.

Synaxial™ thanks you for your confidence and remains at your service for any further information you might require.

Version: 2018

Meaning of pictograms

CE Marking + N° of the Certifying Body

Never reuse

Sterilised by gamma irradiation

Protect from direct sunlight

Use before the expiration date

Refer to operating instructions

Manufacturer

SINUSJET REF SJ1

Do not use if the packaging is damaged

LOT Batch Number

REF Product Reference Number

Synaxial SA
314 Avenue de Messidor
1180 Bruxelles
Belgium

CE 1639