 Manufacturing date

SN Serial Number

REF REF Article number

STERILE Sterilized using steam

Do not re-sterilize

Single patient use

Warnings

Use by date

Do not use if package is damaged

Read the Instruction for Use

Fragile

MR Conditional; See IFU and/or www.ossdsign.com

Unique Device Identifier

34°C 4°C Temperature limit

OssDsign AB
Virdings Allé
SE 754 50 Uppsala, Sweden

O +46(0)18-55 39 93
E info@ossdsign.com
W www.ossdsign.com

OSSDSIGN®

Instruction for Use

OSSDSIGN® Facial PSI
Custom-made device

Please read this instruction prior to clinical application. The instructions must be followed.

Introduction

OSSDSIGN® Facial PSI is an implant intended to augment bone in the maxillofacial region. The implant is custom made to fit the individual patient. OSSDSIGN® Facial PSI is composed of a reinforcing integrated titanium mesh, surrounded by a calcium phosphate-based ceramic. OSSDSIGN® Facial PSI is made from biocompatible materials that allow for host tissue integration.

Intended Use

OSSDSIGN® Facial PSI is intended for the reconstruction of maxillofacial defects. It is indicated for non-load bearing applications for patients in whom maxillofacial growth is complete.

Warnings

• OSSDSIGN® Facial PSI is MR Conditional; see important restrictions under MR Consideration /Safety information.
• OSSDSIGN® Facial PSI shall NOT be used for load bearing purposes.
• Care must be taken to assure that screw placement and length do not interfere with sensitive tissue.
• To ensure secure fixation, the screws must have a screw head that is larger than the hole in the fixation arm.

MR Considerations / Safety information

MR Conditional
Non-clinical testing and in-vivo electromagnetic simulations demonstrate that the Facial PSI is MR Conditional. A patient with this device can be scanned safely in an MRI system after implantation under the following conditions:

• Static magnetic field of 1.5-Tesla or 3-Tesla.
• Maximum spatial gradient magnetic field of 3000 Gauss/cm
• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode) and head average SAR of <3.2 W/kg (Normal Operating Mode)
• Body coil only, do not use head transmit/receive coil
• Quadrature transmit coils only

Under the scan conditions defined above, OSSDSIGN® Facial PSI is expected to produce a maximum temperature rise of 2°C after 15-minutes of continues scanning.

Artifact information
In non-clinical testing, the image artifact caused by the Facial PSI extends approximately 7 mm from the implant when imaged using a gradient echo pulse sequence and a 3-Tesla MRI system.

Contraindications

OSSDSIGN® Facial PSI is not intended for use with:
1. Patients in whom maxillofacial growth is not complete.
2. Infected areas.
3. Procedures or applications other than those described herein.
4. Patients with foreign body sensitivity or metal allergies.

Precautions

1. Before implanting OSSDSIGN® Facial PSI, the surgeon should position the device according to the description in the Procedure section.

2. Incorrectly placed implants may affect the functional and esthetic outcome of the procedure. Before beginning the procedure, assure that all necessary components for the procedure are present.

3. This device may only be used by properly trained and experienced medical personnel working in a sterile operating environment.

4. The surgeon is responsible for proper selection of appropriate patients and procedures, the adequacy of medical personnel training and experience, and all decisions to remove other implants.

5. Radiotherapy after implantation may require alternative dosing to account for the presence of the implant.

6. OSSDSIGN® Facial PSI is carefully designed to fit a specific patient's defect. During placement care should be taken not to damage surrounding soft tissue. Cutting or reshaping of the device is not allowed.

7. Excessive screw tightening may cause loose titanium or bone fragments. Any such fragments must be removed.

8. Excessive screw tightening may cause screws to strip out of the bone intended for attachment. If a screw hole strips out, emergency or self-tapping screws may be used, following the Instructions For Use of the screw manufacturer. Do not use screws of a length that may contact the underlying nerves.

9. Dispose of, and do not implant any product that has been explanted, damaged or mishandled prior to the operation.

10. In case of explantation screws must be removed prior to removal of the implant. The implant integrates into neighboring bone and soft tissue over time, which may affect the surgical procedure.

11. Nerves need to be considered during placement of the device to ensure that they are not exposed to unnecessary mechanical stress.

12. The risk of infection is higher when the device is placed through the oral cavity.

13. Bending of the fixation arms is allowed.

Possible complications

1. Nerve damage of underlying nerves caused by attachment screws.

2. Titanium allergy.

3. Incautious handling of the device may cause smaller ceramic fragments to loosen. Remove the loose ceramic fragment and proceed with implantation.

4. Bone growth or bone resorption may occur from time of CT scan to implantation. This may change the defect, which might cause a poor implant fit.

5. All alloplastic materials including this device may cause post-operative infection.

6. Excessive bending may cause fixation arm to break off.

Sterility

OSSDSIGN® Facial PSI is sterilized by OssDsign using steam sterilization (20 minutes, 121˚C). OssDsign cannot guarantee device sterility if the inner package seal is broken or if the package is improperly opened or the product mishandled. The device may not be re-sterilized.

Storage information

Store between 4-34°C (40-93°F)

Directions for use / Procedure

Step 1

Confirm OSSDSIGN® Facial PSI product labeling, patient ID, expiration date, quantity on hand and intact sterility barrier before starting surgery.

Step 2

The defect is surgically exposed including the periosteum according to the standard procedure. Make sure to remove overlying soft tissue including periosteum.

Step 3

OSSDSIGN® Facial PSI is positioned at the location of the defect to be augmented. Correct positioning should be assessed perioperatively by inspecting the provided visual aid.

Step 4

OSSDSIGN® Facial PSI is fixated to the bone using tapered (counter-sunk) titanium screws, suitable for application in the facial skeleton, inserted into the fixation points.

Step 5

Close wound according to the procedure selected by the surgeon.