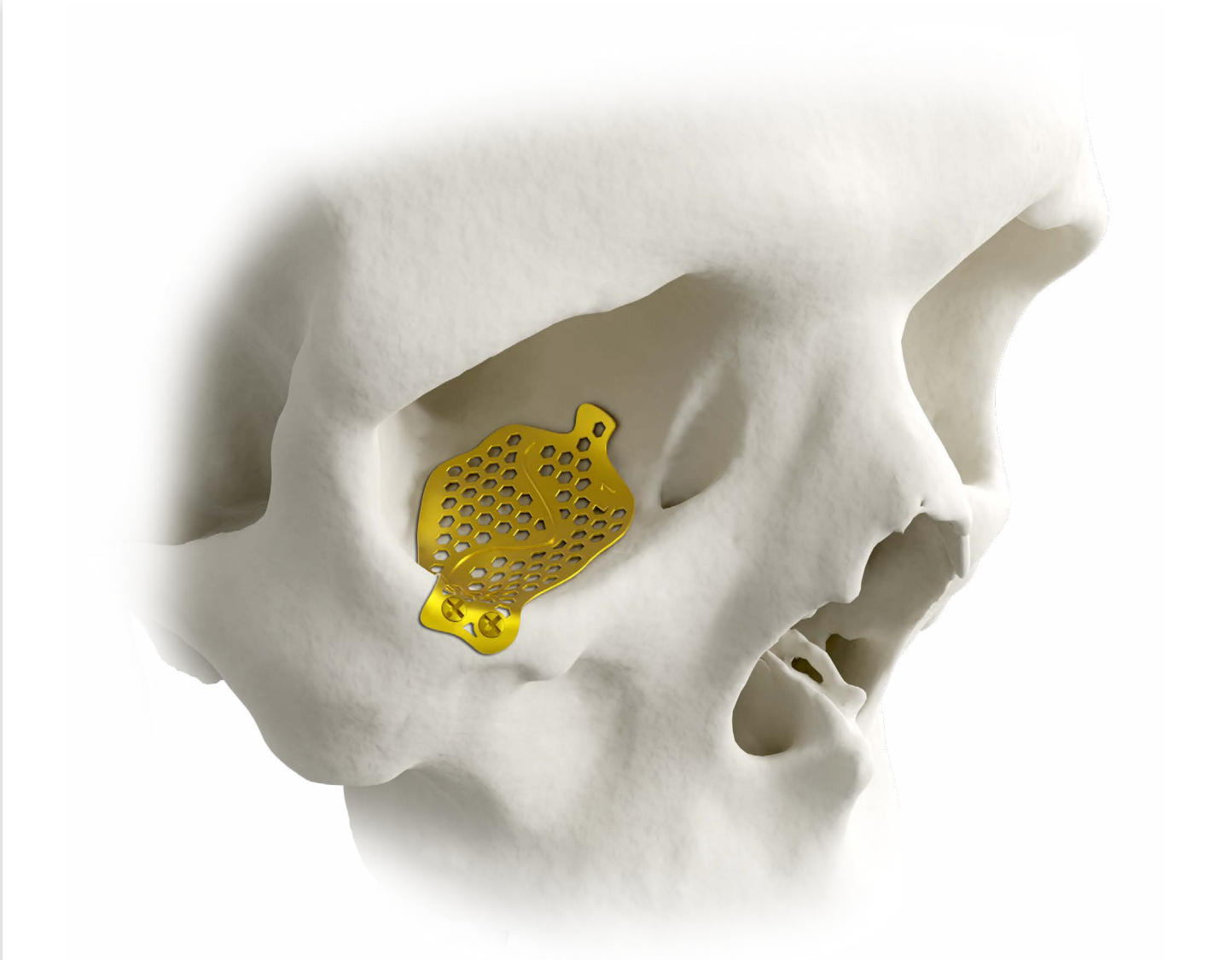
stryker

Facial iD®

System



Operative technique

Product Description

The Facial iD System implant is a customized patient-specific implant based on CT-data and input by the surgeon. Each Facial iD System implant is individually designed to meet the needs of the surgeon and to fit the patient's anatomy.

The Facial iD System implant is supplied non-sterile and can be ordered with an optional Anatomical Model. The Anatomical Model is provided as a preoperative guide to demonstrate the planned reconstruction and the fit of the implant.

The package always contains a Design Proposal, which is a printed summary of the implant design specifications and includes accompanying visualizations of the implant in relation to the patient anatomy.

Important Information

The materials contained in this booklet have been provided for general education information purposes only. The information contained in this booklet cannot and should not replace the independent medical judgement of the treating physician.

As a manufacturer, Stryker does not provide medical advice or services and does not recommend specific techniques or instructions. It is always the responsibility of the treating physician to determine the appropriate treatment and technique, based on the physician's medical knowledge and the individual circumstances of the patient and the particular case. It is also the treating physician's sole responsibility to inform the patient about potential risks, complications, and benefits of certain products and procedures.

Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling.

Consult Instructions for Use (www.ifu.stryker.com) for a complete list of potential adverse effects, contraindications, warnings, and precautions.

Product Material Information

The Facial iD System implant is 3D printed out of commercially pure titanium.

The Anatomical Model is made out of polymer resin.

Product Features

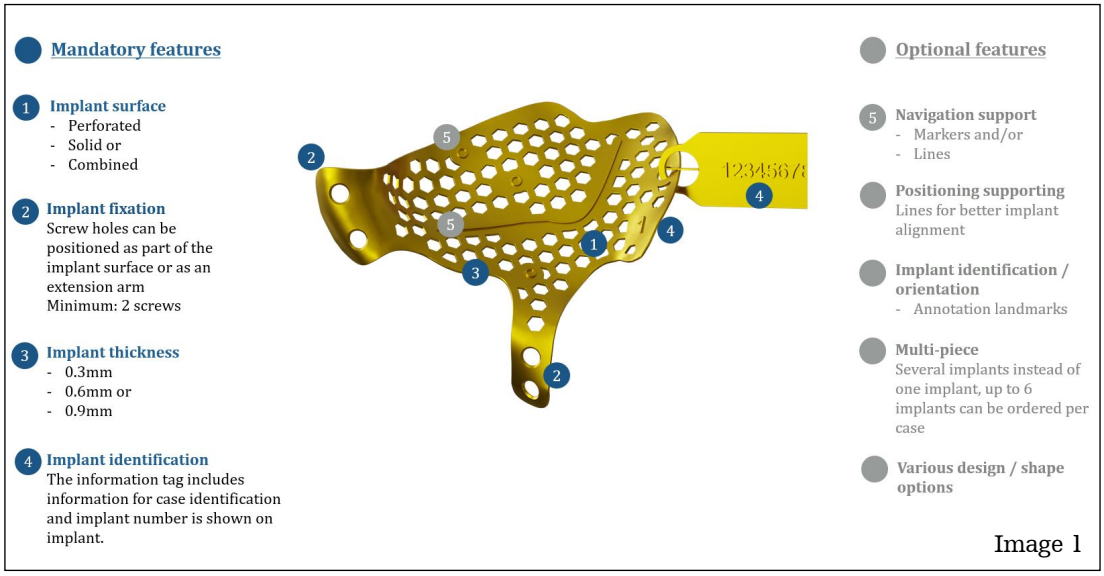


Image 1

Compatible Stryker Products

The Facial iD System is designed to be used with Stryker instruments and Stryker screws.

The following Stryker instruments are recommeded to be used with the implant:

- Bender: Ref. 36-00726
- Cutting instruments: Ref. 62-18330 and Ref. 01-01038 (for cutting off the information tag)

The following Stryker Universal CMF Screws are validated to be used with the Facial iD System:

Screw type (system color)	**Upper-Face** (yellow)	**Mid-Face** (orange)
Self-tapping	1.2/1.2 AXS	1.7/1.7 AXS
Self-drilling	1.2/1.2 AXS	1.7/1.7 AXS
Emergency	1.4/1.4 AXS	1.9/1.9 AXS

Indications for Use

The Facial iD System is intended for osteotomy, stabilization, and rigid fixation of maxillofacial fractures and reconstruction in adults and adolescents (age 12 years and higher).

Specific indications for use:

- Orbital reconstructive/trauma surgery

Contraindications

- Non-reducible and unstable fractures
- Patients with active local infections
- Patients with metal allergies or foreign body sensitivity
- Patients with limited blood supply or insufficient quality or quantity of bone necessary for fixation or stabilization
- Potentially, non-compliant patients who are unwilling or incapable of following postoperative care instructions
- Situations where contact with intracranial contents or exposure of the implant into the intracranial compartment can occur

Operative Treatment Selection

The Facial iD System implant is intended for primary and secondary reconstructive and trauma surgery. The orbital reconstruction includes but is not limited to trauma, tumor.

Orbital reconstruction may be required if orbital bone is comminuted and/or bone fragments are miss-ing or if patient presents with enophthalmos, entrapment, and/or diplopia. Therefore, missing bone is reconstructed. One or multiple Facial iD System implants are then implanted to lift the globe into its pre-traumatized position to recontour the traumatized orbit and to restore the pre-traumatized anatomy.

Particularly in the case of complex and large factures, with loss of bony structures, patient-specific Facial iD System implants can be advantageous because otherwise complex (time consuming) contouring of standard implants would be necessary. Another advantage is the radiopacity, which allows intra- or post-operative radiologic confirmation of placement.

The Facial iD System is only indicated for patients who are selected for a precise treatment according to the medical diagnosis. Adolescents (12 years of age – 21 years of age) and Adults.

The healthcare professional performing any procedure is responsible for determining the appropriateness of using the product and the specific techniques to utilize for each patient.

Special considerations for adolescents patients

The Facial iD System is only indicated for patients who are selected for a precise treatment according to the medical diagnosis. Adolescents (12 years of age – 21 years of age) and Adults.

Special care should be exercised for adolescents patients.

General warnings

- For adolescents patients specifically, inform the patient and the guardian about the additional risks related to the use of the implant in an immature skeleton.
- The use of Facial iD System implant in adolescents patients may lead to growth disturbances of soft tissue and bony structures. This may lead to patient harm, including:
  - loosening of the implant, potentially causing neurological symptoms requiring surgery
  - poor aesthetics, potentially resulting in implant removal.
- Ensure regular follow-up for patients with immature skeleton.

Special care should be exercised when scanning adolescents patients. To reduce the risk of excessive radiation exposure in adolescents patients, the surgeon and/or radiologist should strive to reduce the radiation dose to the amount necessary to obtain clinically adequate images, refer to Stryker's Imaging Protocol.

Scanning specific warnings

- Exposure to ionizing radiation is of concern for adult and particularly for adolescents patients. High radiation dose may lead to patient harm.
  - To avoid rescanning of patients, follow the parameters given in the Stryker Imaging Protocol and use reduced dose and child-sized protocols where appropriate.
  - Consult the instructions for use provided by your imaging device manufacturer and limit radiation dosage to the amount clinically necessary.
  - Comply with the statutory national Diagnostic Reference Levels (DRLs) for pediatric as well as for adult image data examinations.
  - Limit the radiation dosage by reducing the Tube Voltage (kV) and the Tube-Current-Time product (mAs), consider patient size, and activate Tube Current Modulation or Automatic Exposure Control if applicable and indicated for pediatric patients.

Surgical Procedure

Prerequisite

iD Portal (fit.stryker.com) is the Stryker portal used for patient-specific product case initiation, data transfer and case management.

Individual user credentials are required to access. For account creation, please contact your local Stryker Sales Representative or CMFCustomizedImplants@stryker.com

Step 1:
Pre-operative/virtual planning

- Select “Inititate Request” and enter required case-related information (refer to Image 2) und select appropiate application. Then upload patient specific image data (according to Stryker’s Imaging Protocol).
- Afterwards, the input data is checked for its correctness. If the data entered is correct, the data preparation for an optional planning session with the surgeon and an implant proposal is created. As soon as the design is finalized, it will be made available to the surgeon via iD Portal.
- After the physician approved the implant design, the implant is manufactured.
- Before use, ensure that all components that are needed for the operation are available, check that all products belong to the patient and process the products as instructed in the Instruction for Use.

Image 2

Step 2:
Pre-operative preparation
(in case of navigation only)

Download the files for the approved implant design provided by Stryker though iD Portal before surgery.

Warning

- Ensure compatibility of the implant design files with your navigation system before surgery.
- If your navigation system is not compatible, contact Stryker or use an alternative method to control the implant positioning.

Surgical Procedure

Step 3: Incision

Obtain proper exposure of the region where the defect/void exists (e.g., through transconjunctival approach) according to state of the art (refer to Image 3).

Retract soft tissue from the defect area.

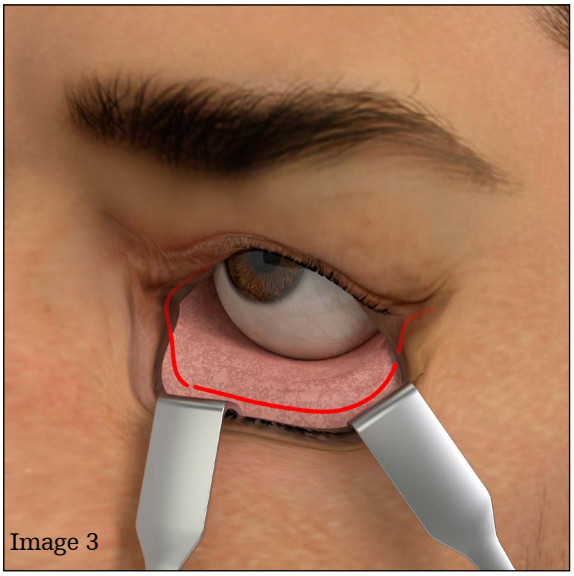


Image 3

If needed, reposition and/or remove bone fragments (refer to Image 4).

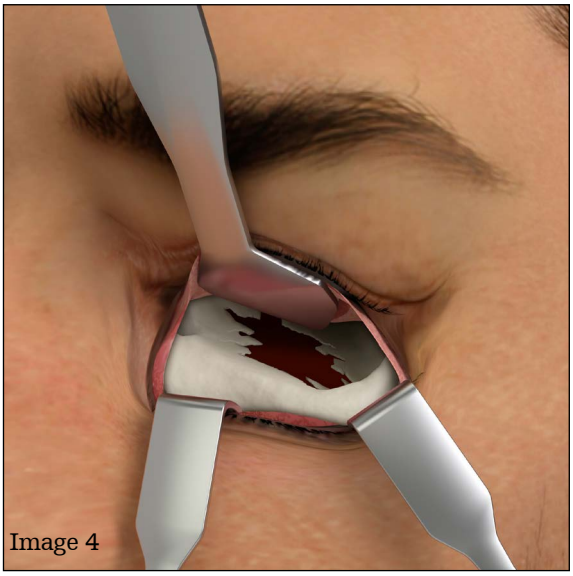


Image 4

Surgical Procedure

Step 4:
Removal of information tag

Remove the information tag from the implant with a cutter (refer to Image 5).

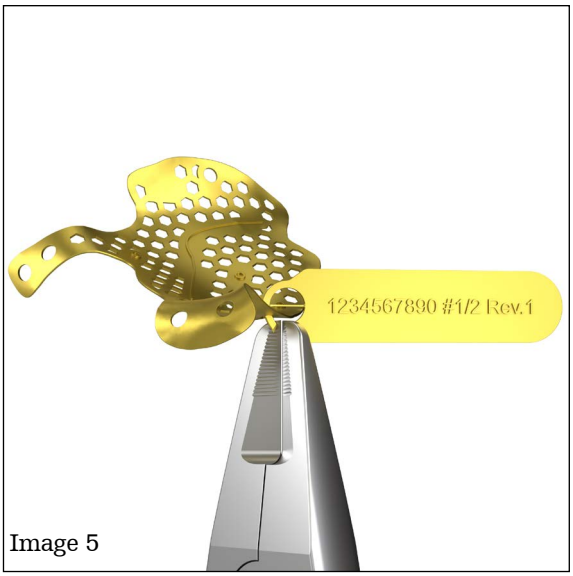


Image 5

Step 5:
Placement of the implant

Position the implant(s) to cover the defect under adequate retraction of the intraorbital soft tissue, ensuring proper fit.

The implant must not impinge on the optic nerve, or structures related to the orbital fissures (refer to Image 6).

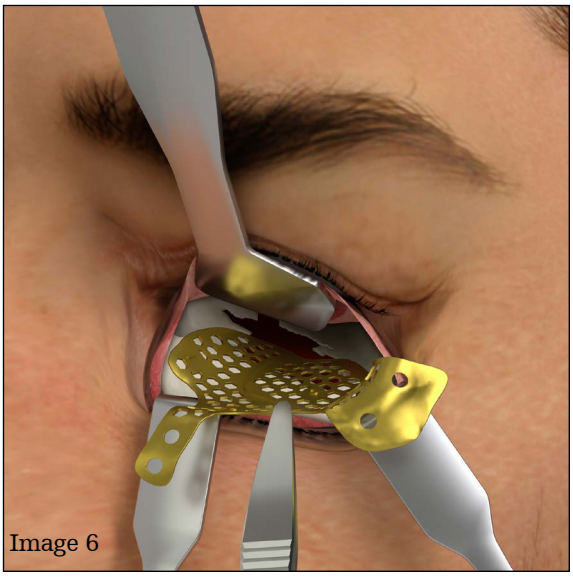


Image 6

Surgical Procedure

Navigation can be used for intraoperative control of implant positioning.

Place the pointer at the navigation lines/markers (refer to Image 7) and check corresponding position on Navigation screen (refer to Image 8).

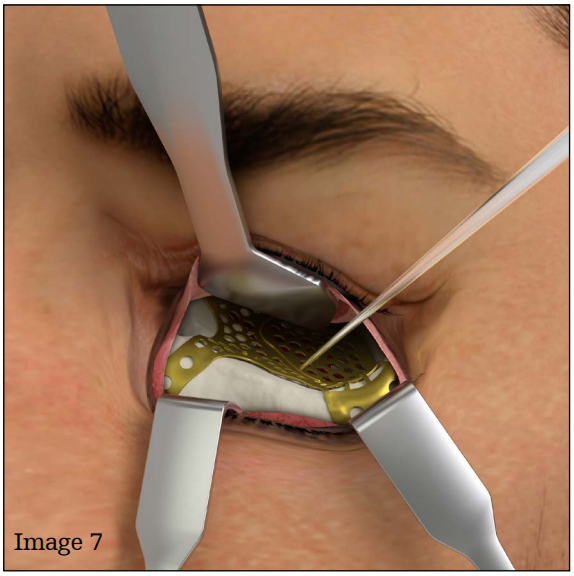


Image 7

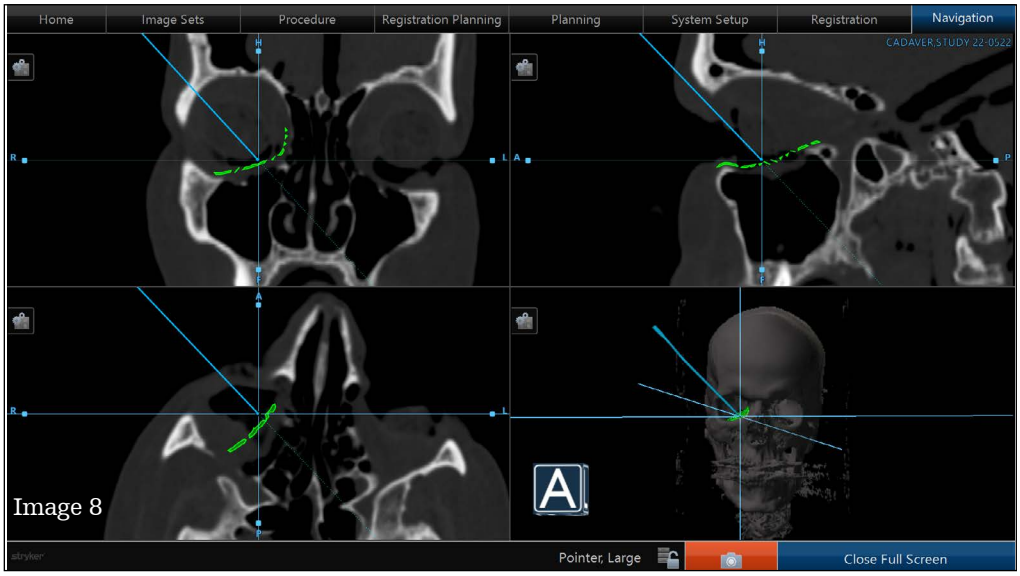


Image 8

Surgical Procedure

Step 6:
Adjustment of the implant (optional)

You may modify the implant by slightly bending.

Step 7:
Secure the implant

Fixate the implant. Insert all planned screws (at least two screws required per implant) until the implant is securely fixed in place (refer to Image 9).

The Facial iD System implant may be fixated using the Stryker Universal 1.2 and 1.7 system.

Caution

Use caution not to over-torque the screw as it may result in deformation, breakage of the screw, or loosening of the screw in the bone.

Confirm implant placement and that implant position allows for adequate clearance of nerves and other relevant structures and that that movement of globe is given.

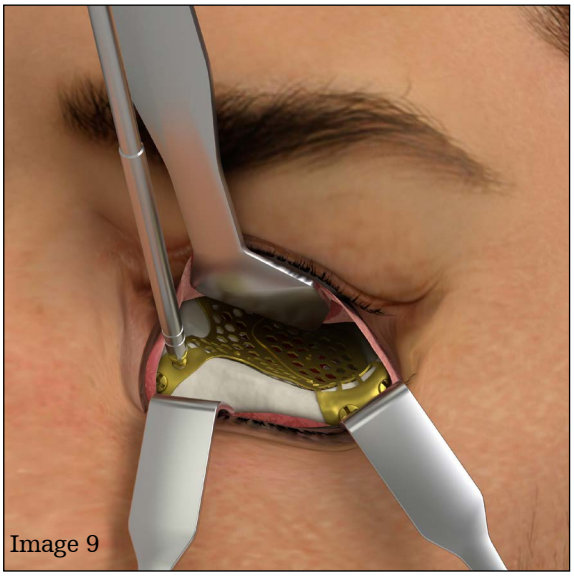


Image 9

Step 8:
Close the incision

Close the incision used for surgical approach in standard fashion.

Step 9:
Implant removal (if necessary)

Generally, implant removal is not necessary except in the event of infection or exposure. The Facial iD System implant is designed for long-term implantation. In general, after the successful surgery, the implant is intended to remain in the human body permanently.

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Craniomaxillofacial

This document is intended solely for the use of healthcare professionals.

A healthcare professional must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that healthcare professionals be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A healthcare professional must always refer to the package insert, product label and/or instructions for use before using any Stryker product.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

The products depicted are CE marked in accordance with applicable EU Regulations and Directives.

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