Acumed Digital Surgery (ADS) Titanium Implants

Instructions for Use

Acumed Digital Surgery (ADS) Titanium Implants

US **These instructions are intended for the Operating Surgeon and supporting Healthcare Professionals. The US instructions are intended for users in the United States and its territories.** Rx only

DESCRIPTION

ADS Titanium Implants are comprised of patient-specific metallic bone plates used in conjunction with commercially available screws cleared by the US FDA, for stabilization, fixation, and reconstruction of the maxillofacial/midface and mandibular bones.

The devices are manufactured based on medical imaging (CT scan) of the patient's anatomy with input from the physician during virtual planning and prior to finalization and production of the device. The physician only provides input for model manipulation and interactive feedback by viewing digital models of planned outputs, modified by trained ADS engineers during the planning session. For each design iteration, verification is performed by virtually fitting the generated implant over a 3D model of the patient's anatomy to ensure that its dimensional properties allow an adequate fit.

Implants are provided non-sterile, range in thickness from 0.6 to 10 mm, and are manufactured using traditional (subtractive) methods from CP Titanium (ASTM F67).

ADS Titanium Implants offer different solutions:

- Reconstruction with free flap of the micro-vascularized fibula.
- Reconstruction with iliac crest flap.
- Reconstruction system for small defects without flaps.

Table 1 below shows part numbers that are included in ADS Titanium Implants.

Table 1. References of ADS Titanium Implants.

Part Number	Part Description
7702-1001L	PTS Le Fort Plate L
7702-1001R	PTS Le Fort Plate R
7702-1001N	PTS Le Fort Plate BL
7702-1002L	PTS BSSO Plate L
7702-1002R	PTS BSSO Plate R
7702-1003N	PTS Genioplasty Plate
7703-1001L	PTS Mandible RECON Graft Plate L
7703-1001R	PTS Mandible RECON Graft Plate R
7703-1001N	PTS Mandible RECON Graft Plate BL
7703-1002N	PTS Mandible RECON Graft Plate NAR
7703-1003L	PTS Mandible RECON Spanning Plate L
7703-1003R	PTS Mandible RECON Spanning Plate R
7703-1003N	PTS Mandible RECON Spanning Plate BL
7703-1004L	PTS Maxilla RECON Graft Plate L
7703-1004R	PTS Maxilla RECON Graft Plate R

7703-1004N	PTS Maxilla RECON Graft Plate BL
7703-1005N	PTS Maxilla RECON Graft Plate NAR
7703-1006L	PTS Maxilla RECON Spanning Plate L
7703-1006R	PTS Maxilla RECON Spanning Plate R
7703-1006N	PTS Maxilla RECON Spanning Plate BL
7703-1007L	PTS Midface RECON Plate L
7703-1007R	PTS Midface RECON Plate R

ACCESSORIES

The ADS Titanium Implants can be used along with plastic anatomic and Implant models. These accessories are optional. DICOM images or optional dental 3D scans are used to design these devices. The final design is approved by the surgeon prior to manufacture.

The anatomic model is a representation of a patient's anatomy used for pre-surgical planning. The model can be used to better understand the pathology and proposed treatment and can also be used to evaluate implant placement.

The implant model is a representation of the implant used during surgery. It can be used along with the anatomical model to assess fitting during the pre-surgical planning.

The anatomic and implant models are manufactured from Clear Resin, Acrylonitrile Butadiene Styrene (ABS) or Polylactic Acid (PLA). These are designed for pre-surgical planning only and are not intended to enter the operating room.

Figure 1 shows an example of an anatomic model:

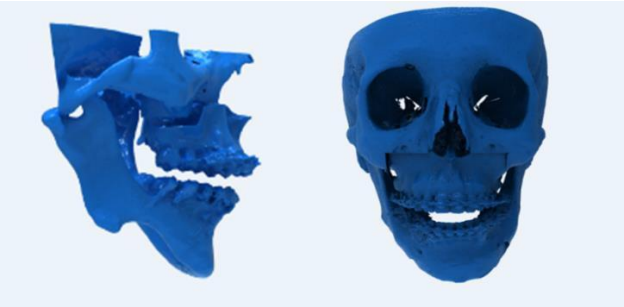

Figure 1. Example of an ADS Diagnostic model (color may differ from image)

FIXATION SYSTEM

ADS Titanium Implants are fixed with commercially available fixation systems cleared by the US FDA under K980760, K160363, K032442, K180204 and K150965. The surgeon indicates in the preparatory plan the type of fixing screws of choice.

In order to ensure compatibility, ADS patient-specific Maxillofacial plates holes design follows ASTM-F543-17, which describes standardized screw parameters. The implant holes are designed according to the technical specifications of the Type HA Screw and the type of driver connections: Combined Cruciate-Slot and Cross-Recessed, and Hexagonal recess; as indicated in ASTM-F543-17, Annexes 5 and 7.

INTENDED USE

ADS Titanium Implants are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial/midface and mandibular skeletal regions.

INDICATIONS FOR USE:

- Primary mandibular reconstruction with bone graft
- Stabilization and rigid fixation of mandibular fractures
- Maxillary reconstruction with or without bone graft
- Maxillary trauma

CONTRAINDICATIONS

Acute and chronic infections; muscle, nerve or vascular diseases that endanger the affected extremity; a lack of bony tissue or poor bone quality (e.g. severe osteoporosis); local bone tumors. Systemic diseases and metabolic disorders; infections and falls; drug dependence; obesity; highly physical activities together with activities involving extreme vibrations which can lead to overstraining of the implants. Patients with confirmed material sensitivity. Patients who are unwilling or incapable of following post-operative care instructions.

POTENTIAL ADVERSE EFFECTS

Implant-specific adverse events include but are not limited to:

- Implants-specific adverse events include but are not limited to:
- Loosening, bending, or breakage of the device
- Non-union, bad-union or delayed union which may lead to breakage of the implant
- Pain, discomfort or abnormal sensation due to the presence of the device
- Infection
- Soft tissue irritation, laceration or migration of the device through the skin
- Allergic reactions secondary to material incompatibility
- Graft failure
- Restricted or impaired bone growth
- Possible transmission of bloodborne pathogens to the user
- Injury of patient
- Soft tissue thermal damage
- Bone necrosis
- Paresthesia

Important: Any adverse event that has occurred in relation to the device should be reported to Acumed through customercomplaints@acumed.net or +1.888.627.9957

MRI SAFETY INFORMATION

ADS Titanium Implants have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifacts in the MR environment. The safety of the ADS

Titanium Implants in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

IMPLANTS

MATERIALS

The ADS Titanium Implants (Plates) are fabricated from biocompatible commercially pure titanium grade 4 according to ASTM F67 standard.

Commercial fixing screws are made from biocompatible titanium alloy (Ti6Al4V) according to ASTM F136 standard.

TECHNICAL SPECIFICATIONS OF ADS TITANIUM IMPLANTS

Table 2 shows the technical specifications of ADS Titanium Plates.

Table 2. Technical specifications of ADS Titanium Plates

Material	Pure Titanium grade 4
Manufacturing Method	CP Titanium: Traditional (Subtractive) / machining
Thickness	Maxillofacial reconstruction: 0.6 mm – 2.0 mm
	Midface reconstruction: 0.6 mm – 10 mm
	Mandibular reconstruction: 2.0 mm – 3.0 mm
Style	Non-compression
	Threaded
Width (screw-hole dependent)	Maxillofacial: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 3 mm (not around screw hole) Max: Dependent on screw-hole
	Midface: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 3 mm (not around screw hole) Max: Dependent on screw-hole
	Mandibular: Min: 6.63 mm - Max: 16 mm
Length	Maxillofacial: Min: 18 mm - Max: 350 mm
	Midface: Min: 18 mm - Max: 350 mm
	Mandibular: Min: 78 mm- Max: 320 mm
Degree of curvature (in-plane)	Maxillofacial/midface: Min: 30° - Max: 180°
	Mandibular: Min: 90° - Max: 180°
Degree of curvature (out-of-plane)	Maxillofacial/midface: Min: 15° - Max: 180°
	Mandibular: Min: 60° - Max: 180°
Hole spacing	Maxillofacial: ≥4.5 mm
	Midface: ≥4.0 mm
	Mandibular: ≥8 mm
	Maxillofacial/midface: Min: ≥ 2 per side of defect Max: Dependent on length & hole spacing

Number of Holes	Mandibular: Min: 4 Max: Dependent on length & hole spacing

PROCESSING

CLEANING

Implants are packaged clean but not sterile. They must be sterilized before use. Avoid shock, scratches, and contact with other objects that may cause damages on the surface or shape, such as marks, notches, debris, discoloration, abrasion, or residues.

STERILIZATION

ADS Titanium Implants must be sterilized before use. The following sterilization instructions are recommended:

Pre-Vacuum Steam Sterilization	ADS Titanium Implants
Exposure Temperature:	270°F (132°C)
Exposure Time:	4 minutes
Dry Time:	30 minutes
Configuration[1]	Wrapped
[1] The use of an FDA-cleared wrap during the sterilization process is required. It is recommended to use double pouched 5.5'' x 10'' and 7.5'' x 13'' pouches (Cardinal Health self-sealed pouch CAT #92510, 92713 – 510 (k) K153540).	

STORAGE CONDITIONS

HANDLING

The implants should be unpacked and handled carefully to avoid damage on surface or geometry, such as scratches, marks, notches, debris, discoloration, and abrasion (corrosion) caused by contact with other implants, instruments, tools or falling.

In order to ensure the correct performance of the implants, the surgeon must follow the specific surgical techniques and follow the indications of the system. Implants should not be bent, scratched, notched, or modified.

Patients must avoid physical activities that generate stress on the implant or the bone fragment until the fracture has fully healed.

The removal of the implant must be done according to medical criteria.

TRANSPORT

The implants must be carefully transported inside their box to avoid damages that may alter the technical details.

STORAGE

The implants must be stored in a dry, clean environment, at temperatures ranging from -20°C to 50°C and relative humidity range from 10% to 75%.

The implants have a lot number in the packing label and on the surface, these marks allow for easy the inventory control, medical reports, and to keep implant traceability. Lot number must be indicated in the patient's history.

The implants must be stored separately from implants made with different materials.

Symbols Glossary

Symbol	Description	ISO 15223-1
	Consult the electronic instructions for use (eIFU) at www.acumed.net/ifu	5.4.3
	Non-sterile	5.2.7
	Catalogue number	5.1.6
	Batch code	5.1.5
	Manufacturer	5.1.1
	Date of manufacture	5.1.3
	Do not re-use	5.4.2
	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.	U.S. 21 CFR 801.109
	The reticle is a registered trademark of Acumed. It may appear alone or with the Acumed name.	

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