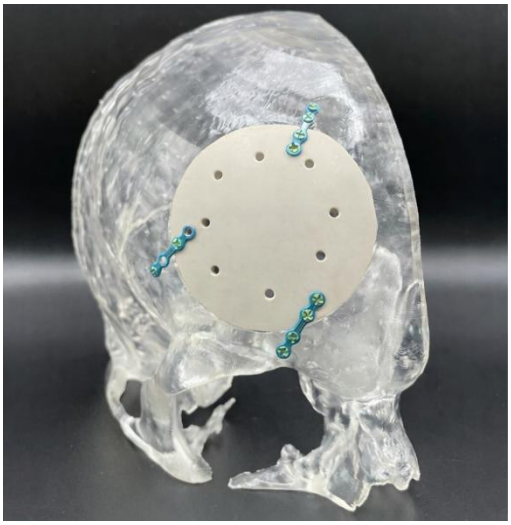
# Acumed Digital Surgery (ADS) PEEK Cranial Implants



# Instructions for Use

## Acumed Digital Surgery (ADS) PEEK Cranial 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 PEEK Cranial Implants replace bony voids in the cranial skeleton. The devices are attached to the native bone using commercially available plates and screws cleared by the US FDA. ADS PEEK Cranial Implants are manufactured from Polyether Ether Ketone (PEEK) through machining.

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. ADS PEEK Cranial Implants are provided non-sterile.

Depending on the surgeon's preference and patient's anatomy, ADS PEEK Cranial System may be designed varying their thicknesses from 3.0mmup to a maximum thickness of 4.2mm. ADS PEEK Cranial System can be manufactured including the fixation holes or not.

*ACCESSORIES*

*Cranial models*

The ADS anatomic models are patient-specific devices that represent the anatomy of the patient and are intended to be used as a pre-operative planning tool for treatment in the field of cranial surgery.

The models are created from a CT scan of the patient's anatomy, which is segmented through Commercial-Off-The-Shelf (COTS) software and converted into virtual 3D models. The surgeon uses these 3D models to make the initial plan/diagnosis based on examination or physical measurement of the patient´s anatomy, the resections, measurement of anatomic distances (e.g., the cranial symmetry), and determining fixation points and the size and shape of the implants if requested. These functions are those that the surgeon can perform, not functions that the subject device provides by itself.

ADS creates a design proposal for the case based on the information given by the medical professional and the process continues until the final design proposal is approved. Finally, the digital file can be used as an input to produce physical anatomic models through additive manufacturing.

*ADS Digital Planning Software*

The ADS Digital Planning Software is aweb-based collaboration software for case management and cranial surgery planning and allows for the interaction of multiple users: surgeons, sales representatives, and the ADS case planning staff allowing for easy collaboration in the planning process.

*Fixation System*

ADS PEEK Cranial Implants are attached to the native bone using commercially available plates and screws to offer diverse options to the surgeon. The recommended plates and screws for fixing ADS PEEK cranial implants are commercially available cranial plates - CP Ti Grade 1,2,3, and 4 TiAL6V screws.

## INDICATIONS FOR USE

The ADS PEEK Cranial Implants are intended to replace bony voids in the cranial skeleton. The ADS PEEK Cranial System includes cranial models and a software component, the ADS Digital Planning Software.

The devices are indicated for adults and adolescents from 18 years.

## 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 implants overstraining.

The fixation system must be manufactured from CP Titanium (ASTM F67) or Titanium alloy Ti6Al4V (ASTM F136). The use of dissimilar metals may accelerate the corrosion process due to galvanic corrosion effects.

## WARNINGS AND PRECAUTIONS

### Warnings

- Do not allow the interaction of the Anatomic and ADS Diagnostic Models with ADS PEEK Cranial Implants. These models are non-sterile and should not interact with the elements that are intended to be implanted during surgery.
- Internal fixation devices cannot withstand activity levels and/or loads equal to those placed on normal healthy bone. These devices are not designed to withstand the unsupported stress of full weight bearing or load bearing.
- Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

### Precautions

- Surgical implants must never be reused.
- Correct handling of the implant is extremely important. Contouring of metallic implants should be avoided where possible. If contouring is necessary, or allowed by design, the surgeon should avoid sharp bends, reverse bends, or bending the device at a screw hole. The operating surgeon should avoid any notching or scratching of the device when contouring it. These factors may produce internal stresses which may become the focal point for eventual breakage of the implant.
- Removal after fracture healing. Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture has healed, particularly in young, active patients. While the surgeon must make the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management to avoid refracture.
- Patients must avoid stress-generating physical activities on the implant or the bone fragment until the fracture has fully healed.

## POTENTIAL ADVERSE EFFECTS

Implant-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
- Metal sensitivity
- Limb shortening due to compression of the fracture or bone resorption
- Decrease in bone density
- Nerve damage due

**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

## SURGICAL TECHNIQUE

Regardless of screw size and type, a pilot-hole must be made before placing the screws in the implant. Screw holes must be predrilled outside the surgical site. PEEK patient-specific implants require minimal (if any) modification. For minor fit modifications, it is suggested that the surgeon modifies the patient bone rather than modifying the PEEK patient-specific implant. PEEK patient-specific implants can be modified with a high-speed burr if needed. It is suggested for PEEK implants to be modified and rinsed in sterile saline solution outside from the implant/surgical site, to ensure that particulate debris does not infiltrate the surgical site after any modifications.

## LIFETIME

The shelf life of ADS PEEK Cranial Implants is 90 days. This means that the maximum allowed time between the date of the CT scan and the surgery is 90 days. Performing surgery after this period is at the surgeon's risk.

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

# IMPLANTS

## MATERIALS

PEEK (Polyether ether ketone): ADS PEEK Cranial implants.

Commercially Pure titanium (ASTM F67): Fixation System

Titanium alloy (Ti6Al4V) (ASTM F136): Fixation System

Warning: The use of dissimilar metals may accelerate the corrosion process due to galvanic corrosion effects.

## PROCESSING

### CLEANING

**IMPORTANT:** 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 to the surface or shape, such as marks, notches, debris, discoloration, abrasion, or residues.

### STERILIZATION

Devices from ADS Peek Cranial Implants must be sterilized before use. The following sterilization instructions are recommended:

1. Place the devices in the appropriate block (kit or tray) using forceps and/or powder free gloves to avoid contamination and any other negative effect on the surface of the device.

2. Wrap the block with a surgical drape.

3. Sterilize in the autoclave validated and maintained in accordance with ISO 17665 and ANSI AAMI ST79. Following are parameters validated in accordance with ISO 17665-1 and are recommended for sterilization:

| Pre-Vacuum Steam Sterilization | ADS PEEK Cranial Implants |
|---|---|
| Exposure Temperature: | 270°F (132°C) |
| Exposure Time: | 4 minutes |
| Dry Time: | 20 minutes |
| Configuration[1] | Wrapped |

*[1] The use of an FDA-cleared wrap during the sterilization process is required. It is suggested to double pouch the devices in 5.5'' x 10'' and 7.5'' x 13'' pouches (Cardinal Health self-sealed pouch CAT #92510, 92713 – 510 (k) K153540).*

## STORAGE CONDITIONS

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 markings allow for easy inventory control, medical reports and traceability of the implants. The lot number must be indicated in the patient's history.

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

**SINGLE USE**

ADS PEEK Patient-Specific Cranial Implants are designed for single use and must not be reused.

**HANDLING**

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

**TRANSPORT**

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

## 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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