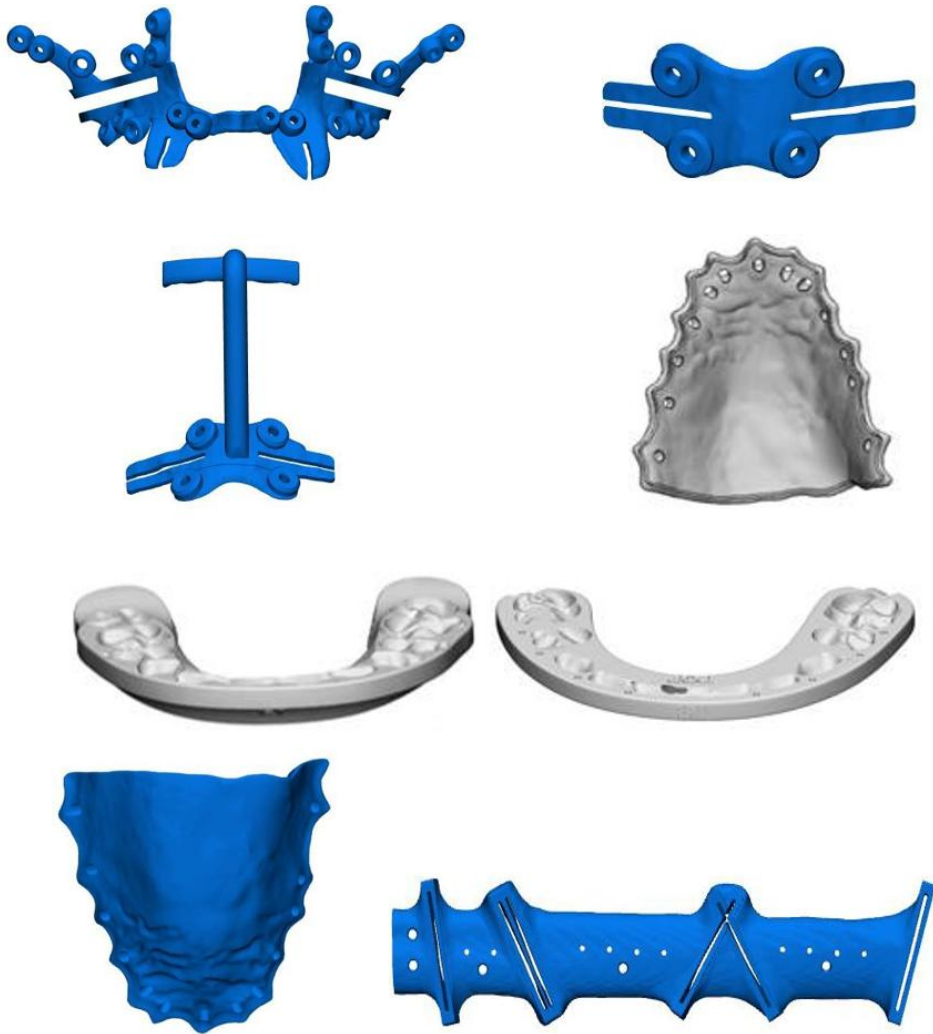


Acumed Digital Surgery (ADS) Craniomaxillofacial (CMF) Guides

US Instructions for use2



Instructions for Use

Acumed Digital Surgery (ADS) Craniomaxillofacial (CMF) Guides

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

The ADS CMF Guides are indicated as a pre-operative tool to support the diagnostic and treatment planning process of maxillofacial procedures by providing surgical guides and splints.

ADS CMF Guides are Patient-Specific single-use devices designed to assist surgeons in transferring the pre-surgical plan to the operation room. This system includes surgical guides intended for Orthognathic and Reconstructive surgeries in adults. The surgical guides have drilling holes and slots to make osteotomies and ensure the correct positioning of bones and implants. The ADS CMF Guides are divided into two categories: ADS Orthognathic Guides and ADS Reconstruction Guides.

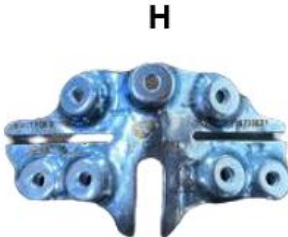
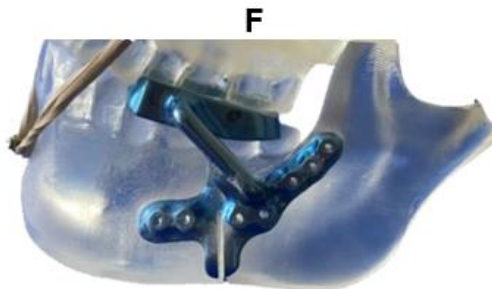
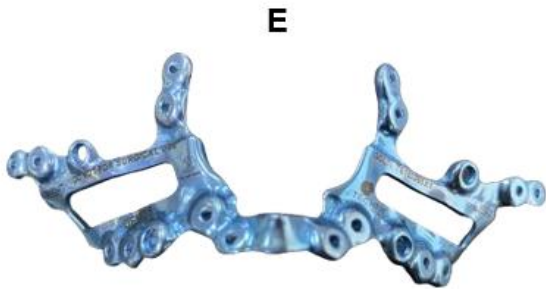
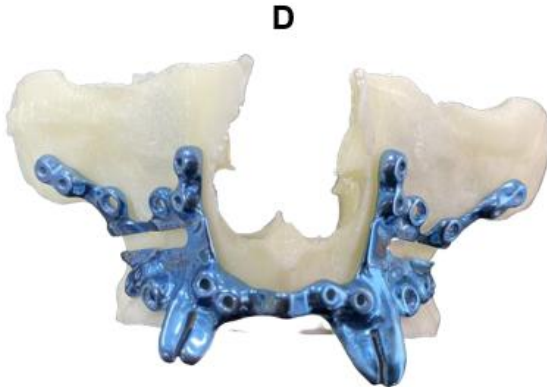
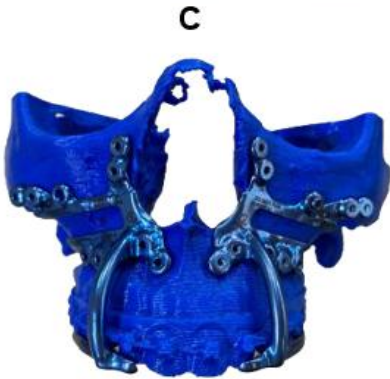
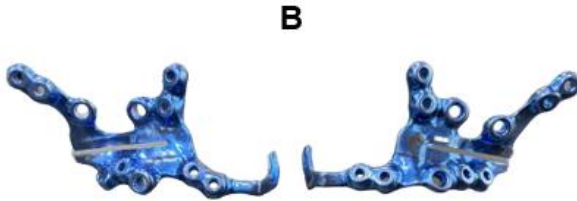
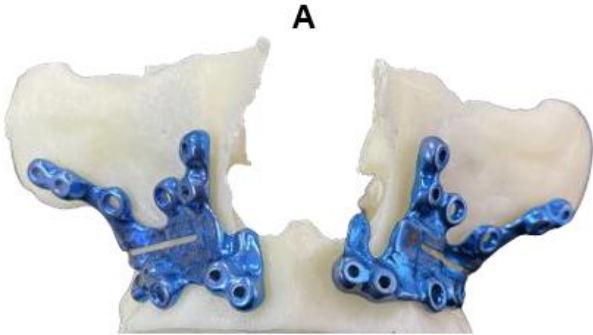
ADS Orthognathic Guides are classified into Titanium and Resin Surgical Guides.

ADS Orthognathic Titanium Guides are manufactured from Commercially Pure (CP) Titanium grade 4; they include mandibular and maxillofacial surgical guides with or without dental support (e.g. Le Fort, Genioplasty, Bilateral Sagittal Split Osteotomy (BSSO) Surgical Guides, etc.). Palatal Splints are also part of ADS Orthognathic Titanium Guides, which are optional guides used in orthognathic surgery to guide and support the correct teeth positioning and validate the patient's final occlusion.

ADS Orthognathic Resin Guides are manufactured through rapid prototyping using the Form 3B and Form 4B printers and Biomed Clear Resin from Formlabs. The resin guides also include splints (intermediate, final, and palatal), which are optional guides used in orthognathic surgery to guide and support the correct teeth positioning and validate the patient's final occlusion.

The ADS Reconstruction Guides are intended for mandibular and maxillofacial surgical procedures in adults, using patient grafts/flaps for reconstruction. These guides are made from Commercially Pure (CP) grade 4 titanium, produced through machining and are finished with an anodizing process. They are intended for use in various anatomical sites, including the maxilla, mandible and fibula. The reconstruction guides ensure precise transfer of the pre-surgical plan to the operating room, facilitating the correct placement and fixation of the patient's bone grafts/flaps at the surgical site.

Figure 1 shows an example of the devices included as part of the ADS Titanium Orthognathic and Reconstruction Guides.



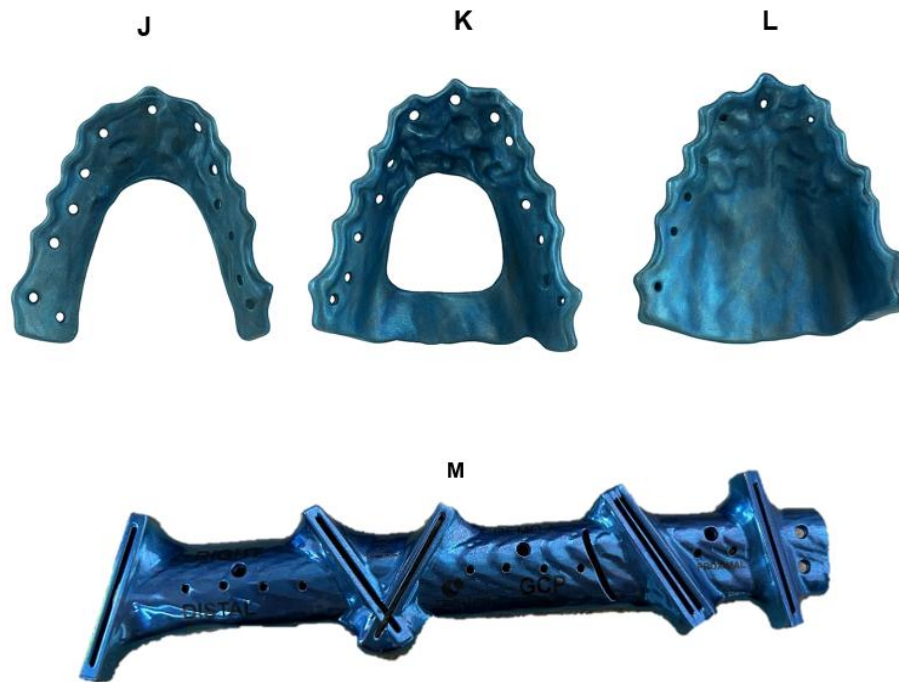


Figure 1. Devices included as part of the ADS Titanium Guides. (A and B) Left and Right Le Fort surgical guides without dental support. (C) Two-time Le Fort surgical guide with dental support. (D and E) Bilateral Le Fort surgical guides without dental support. (F) BSSO surgical guide with dental support. (G and H) Genioplasty surgical guides without dental support. (I) Genioplasty surgical guide with dental support. (J) Horseshoe Shape Palatal Splint. (K) Window Palatal Splint. (L) Complete Palatal Splint. (M) ADS Fibula Guides.

Figure 2 shows an example of the devices included as part of the ADS Resin Guides.

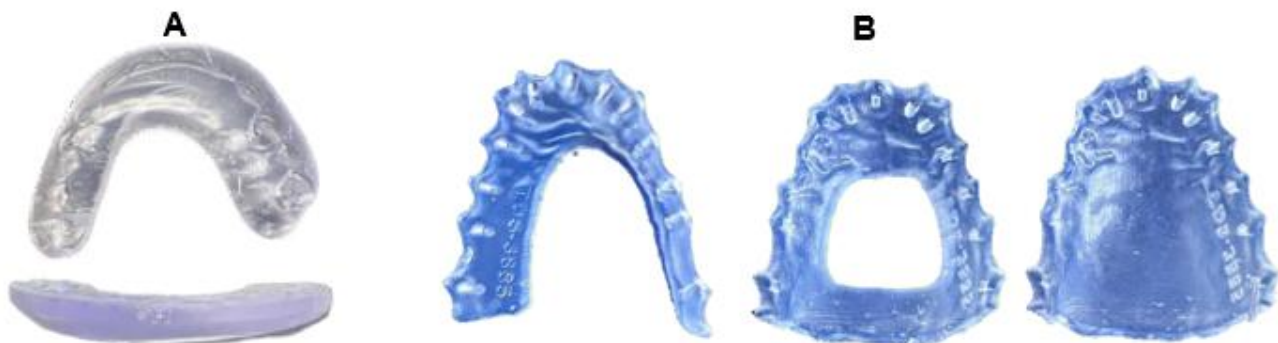


Figure 2. Devices included as part of the ADS Resin Guides. (A) Intermediate and Final Splint. (B) Palatal splints.

Sometimes the ADS Guiding System can be a combination of ADS resin and titanium guides. These parts, made of either resin and titanium, are manufactured and sterilized separately, and during surgery, they are assembled according to preoperative planning. See Figure 3.

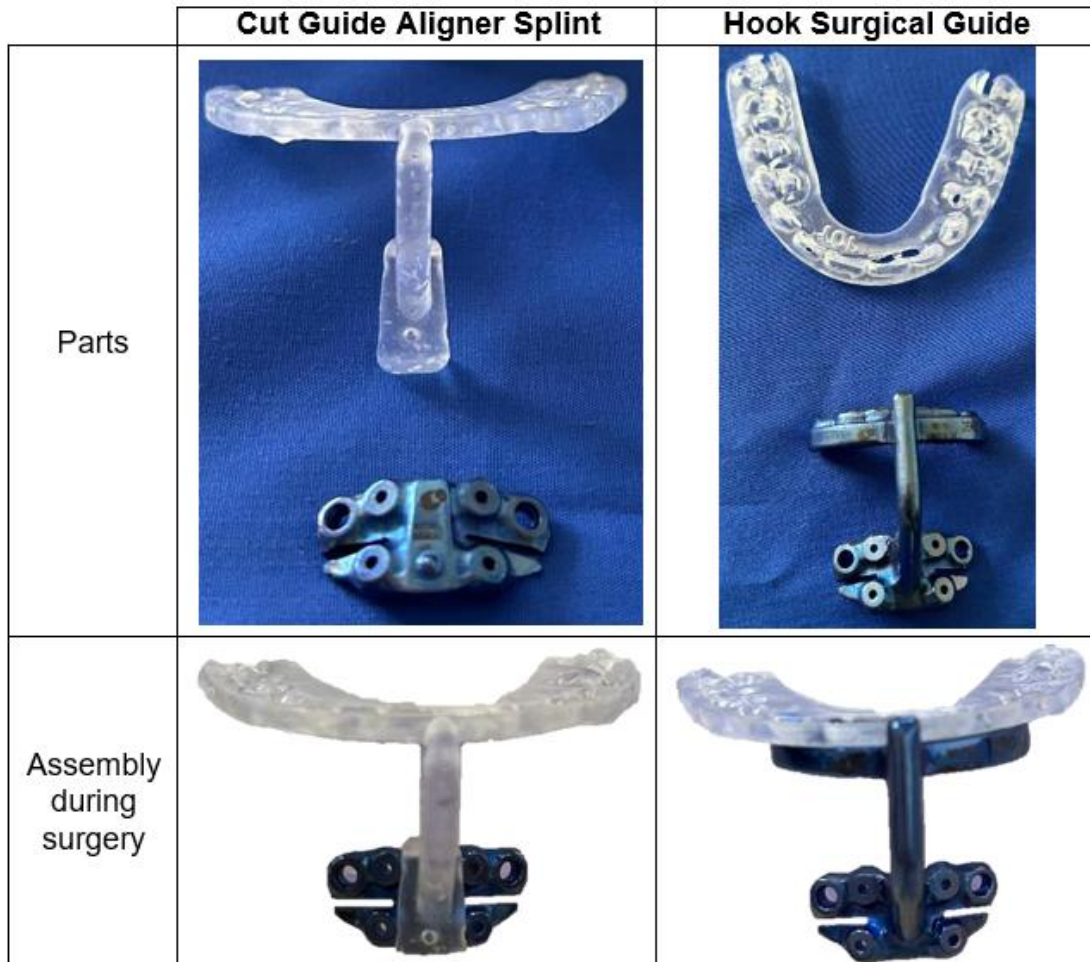


Figure 3. Cut Guide Aligner Splint and Hook Surgical Guides.

INTENDED USE/ INDICATIONS FOR USE

ADS Digital Planning Software System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the Digital Planning Software System, and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including surgical guides and splints for use in maxillofacial surgery.

The ADS Digital Planning Software System is also intended as a preoperative software tool for simulating / evaluating surgical treatment options. The Digital Planning Software system is compatible with the ADS Patient-Specific Maxillofacial System and the ADS Diagnostic Models and should be used in conjunction with expert clinical judgment.

CONTRAINDICATIONS

- Do not implant ADS CMF Guides, they are for transitory use only.

- The physician is responsible for planning and utilizing palatal splints, as well as deciding on their shape and how they are temporarily secured onto the patient.
- Titanium Palatal splints are intended for prolonged contact (24 hours to 30 days), while Resin Palatal Splints are intended for limited contact (≤ 24 hours).
- When using the ADS CMF Guides, clean the operating area since debris could be generated.
- Do not reuse ADS CMF Guides. They are intended for single use only.
- Anatomic CMF Guides are patient-specific devices. Do not attempt to use it in a different patient or anatomy.
- Do not use ADS CMF Guides if the patient's anatomy has changed significantly since the time the DICOM images or 3D scan data were taken.

POTENTIAL ADVERSE EFFECTS

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

LIFETIME

The shelf life of ADS CMF Guides is 90 days. ADS CMF Guides shelf life is defined as the time between the CT scan and the surgery. This shelf-life is a conservative time frame estimate during which patient's anatomy should not have noticeable changes that would compromise the accuracy of the ADS CMF Guides. After this period, the use of ADS CMF Guides is at the surgeon's risk.

INSTRUMENTS

MATERIALS

ADS CMF Titanium Guides (Orthognathic and Reconstruction) are manufactured from biocompatible commercially pure titanium grade 4 according to ASTM F67 standard.

ADS CMF Orthognathic Resin Guides are manufactured from Biomed Clear resin.

PROCESSING

CLEANING

ADS CMF Guides are clean but not sterile packaged, they must be sterilized before use.

STERILIZATION

ADS CMF Guides are delivered non-sterile and require sterilization before use. The recommended sterilization method is pre-vacuum steam sterilization. The table below shows the recommended sterilization parameters:

Pre-Vacuum Steam Sterilization	ADS CMF Guides	
	ADS Resin Guides	ADS Titanium Guides
Exposure Temperature:	270°F (132°C)	270°F (132°C)
Exposure Time:	4 minutes	4 minutes
Dry Time:	30 minutes	40 minutes
Note: For the titanium and resin parts of the Cut Guide Aligner Splint and Hook guides, the titanium parts are sterilized according to Table 1 for ADS Titanium Guides, while the resin parts follow the instructions for ADS Resin Guides.		

STORAGE CONDITIONS

HANDLING

- The ADS Titanium Guides should be unpacked and handled carefully to avoid damage to the surface or the geometry, such as scratches, marks, notches, debris, discoloration, and abrasion (corrosion) caused by contact with instruments, tools, or falling.
- The ADS Resin Guides should be unpacked and handled carefully to avoid damage to the surface or to the geometry.
- To ensure the correct performance of the ADS CMF Guides, the surgeon must follow standard surgical techniques and the indications of the system.
- Guides that interface with dental splints are assembled during surgery.










TRANSPORT

- The ADS CMF Guides must be carefully transported inside the packaging to avoid damages that may alter the technical details.

STORAGE

- The ADS Titanium Guides must be stored in a dry and clean environment, at temperatures ranging from -20°C to 50°C and relative humidity from 10% to 75%.
- Before use, the ADS Guiding System should be stored separately from devices made with different materials.
- ADS CMF Guides must be stored protected from direct sunlight.
- Before use, the ADS CMF Guides should be stored in places where the shape is not altered.

Symbols Glossary

Symbol	Description	ISO 15223-1
 www.acumed.net/ifu	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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