MedCAD®

ACCUPLATE PATIENT-SPECIFIC PLATING

INTRODUCTION

AccuPlate Patient-Specific Plates are individually engineered for patient-specific use according to surgeon specifications. Pre-planning dictates customized plate decisions, minimizing the need for intraoperative adjustments.

INDICATIONS FOR USE

The MedCAD AccuPlate Patient-Specific Plate is intended for prescription use in oral and maxillofacial surgery, trauma and reconstructive surgery.

Specific Indications for Use:

- Primary mandibular reconstruction with bone graft
- Temporary bridging until delayed secondary reconstruction
- Secondary mandibular reconstruction
- Comminuted mandibular fractures
- Fractures of edentulous and/or atrophic mandibles
- Unstable mandibular fractures
- Maxillary reconstruction with or without bone graft
- Maxillary trauma

CAUTION:

AccuPlate has not been evaluated for safety and compatibility in the MR environment. AccuPlate has not been tested for heating or migration in the MR environment. The safety of AccuPlate in the MR environment is unknown. Exposing the patient to MRI following implantation of the device may result in injury.

# ACCUPLATE ADVANTAGES

PATIENT-SPECIFIC SOLUTIONS

Patient-specific plates originate from a patient CT scan. With surgeon input, MedCAD biomedical designers provide a customized reconstruction solution.

FAST RESPONSE

Upload a CT to MedCAD.com for quick response from the MedCAD biomedical design team. Receive updates along the way and meet the need for time-sensitive delivery.

CUSTOMIZABLE

Plating design includes predictive screw holes that are uniquely placed to avoid contact with sensitive anatomy (i.e. nerves, roots). Digital models of anatomy are used to further mitigate unwanted screw contact during planning phases.
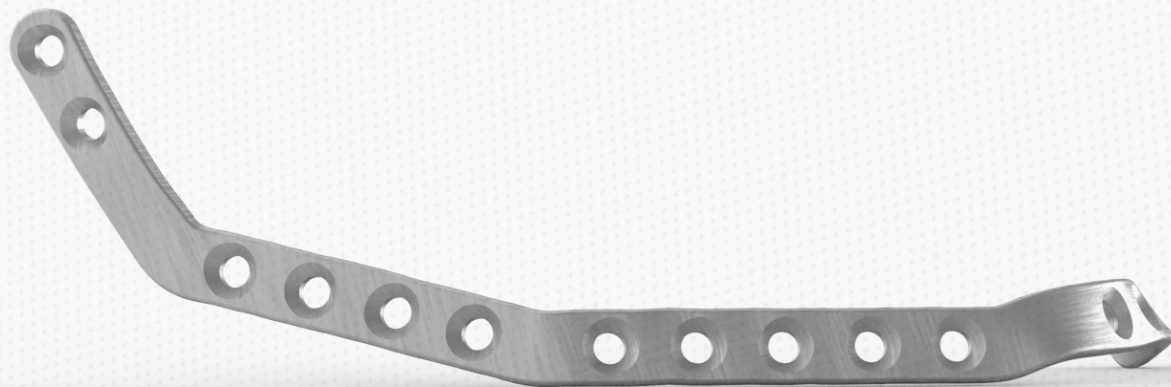

CAUTION:

Surgical implants must never be reused. An explanted metal implant must never be re-implanted. Even if the device does not appear to be damaged, it may have small defects including internal stress patterns which could lead to breakage.

SCREW VISUALIZATION

Screw hole positions are defined individually per physician input to avoid screw interference with nerves, tooth roots, osteotomies, existing, or future implants. Screw length prediction of screw positions allow physician to pre-visualize treatment options.
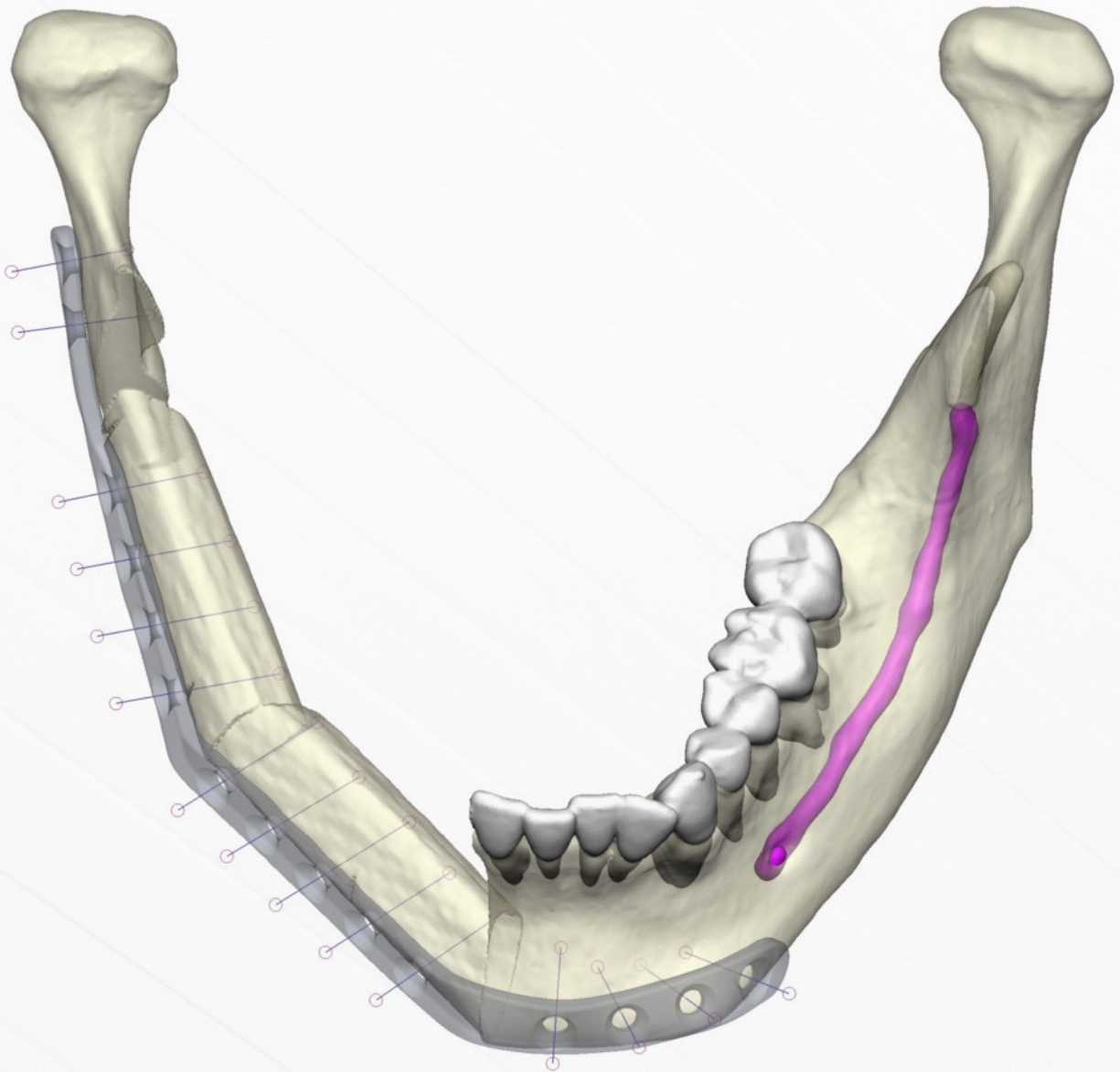
WORKFLOW

1. SUBMIT CT AND CASE INPUT

CT/CBCT/MRI scan data (DICOM), or digital model (STL file) is required for case initiation.

Submit Scan/STL Model:
Upload data via MedCAD.com/upload, or FedEx to MedCAD via MedCAD.com/ship.
(Additional instructions can be found at MedCAD.com/resources)

Submit Service Request:
A service request / order form is required for case initiation.
(Download from MedCAD.com or ask your representative)
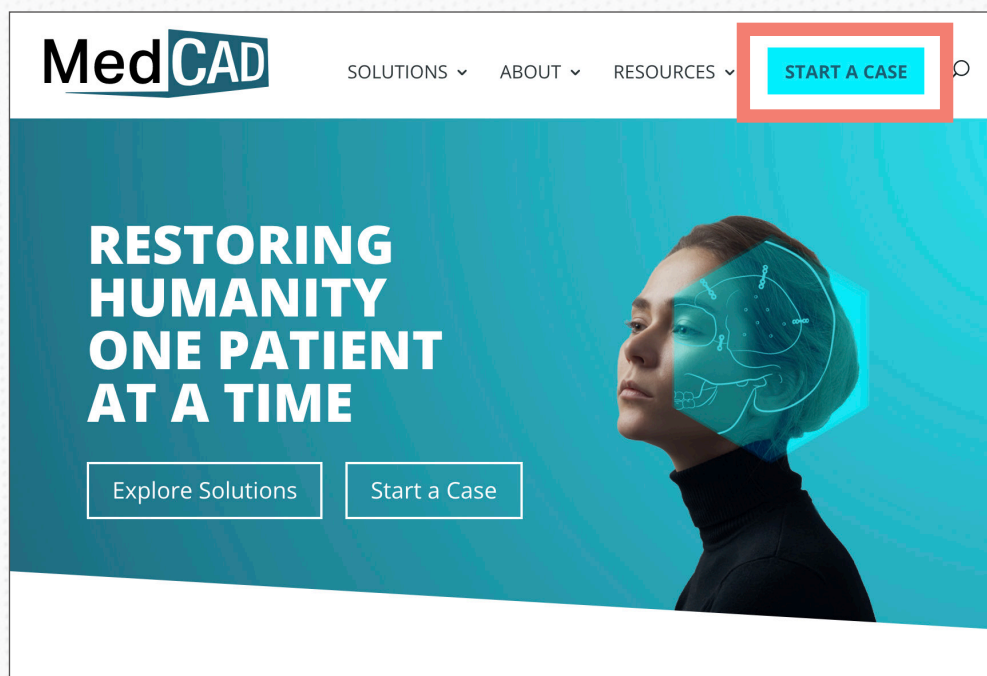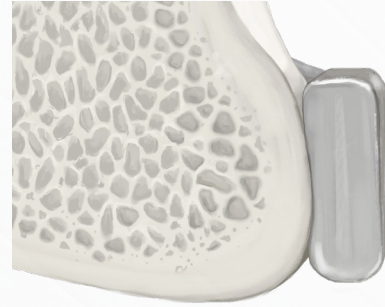

2. DESIGN

Planning Session:
Planning sessions are conducted with MedCAD personnel to begin the plate design and provide information needed to proceed with customization. The information gathered from the physician during a planning session helps dictate the plate design.

DESIGN

2.1 CHOOSE PLATE PROFILE

MedCAD's AccuPlate is designed according to information provided by CT scan data and input from the physician.

Physicians can choose a plate profile of 2.0, 2.6 or 2.8 mm thick.

2.2 DESIGN PLATE

Physician input is used to indicate the position, anatomical location, plate contours, and length. The patient-specific plate must have a minimum of four (4) fixation holes, and may be designed up to a maximum of 490 mm in length. The length of the plate will be defined by the patient anatomy.

General representations of the four (4) identified anatomical locations for which the device is defined is shown below.
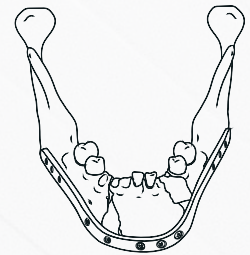
Mandible, Hemi: Includes any smaller implant on a single surface of the mandible. May come in the form of Left or Right.
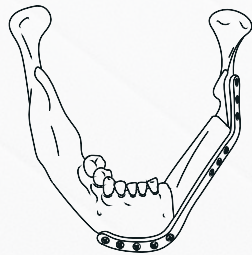
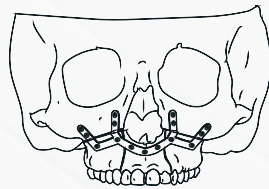**Mandible, Angle-to-Angle:** Includes a single implant that starts at one angle and continues to the other angle.
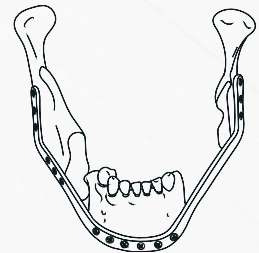
Maxilla: Includes any implant on the maxilla.

Mandible, Condyle-to-Condyle: Includes a single implant that starts at one condyle and continues to the other condyle.

NOTE:

All plates, regardless of anatomical application, must comply with the overall design envelope.

SPECIFICATIONS

MedCAD Plate	2.8mm Plate	2.6mm Plate	2.0mm Plate
Range of Lengths	36 mm - 490 mm	36 mm - 490 mm	30 mm - 490 mm
Distance Between Holes (Minimum)	9.0 mm	9.0 mm	7.5 mm
Degree of Curvature (In Plane)	90º – 180º		
Degree of Curvature (Out of Plane)	60º – 180º		
Shape Designs	Mandible Hemi (L or R) Mandible Angle to Angle, Mandible Condyle to Condyle, Maxilla		
Height (Minimum)	8.25 mm		
Chamfer Angle	90°		
Corner Radius	0.5 mm		

2.3 SELECT SCREWS

AccuPlate allows physicians to choose from multiple screw options. Screw locations are determined according to information provided by:

- Surgeon input
- Osteotomy or resection site
- Patient anatomy such as teeth roots and nerves
- Existing or future implants including, plates, screws, or dental implants

Screw Manufacturer	Zimmer Biomet
Screw Name	TraumaOne™ Plating System
Screw Diameters	2.0mm, 2.3mm, 2.7mm
Screw Lengths	5.0mm - 18.0mm

WARNING:

Correct selection of the implant is extremely important. The potential for success of fracture fixation is increased by the selection of the proper shape, size, and design of the implant. Orient the plate as indicated on the Case Report. If applicable, use the patient-specific plate or case report as a guideline to determine the appropriate screw size and type, locking or non-locking.

APPROVAL AND MANUFACTURING

3. SURGEON APPROVAL

Approval is required for manufacturing and shipping AccuPlate.

Surgical Plan for Approval:
Planned surgical outcome and patient-specific plate design are organized in a comprehensive visual Case Report. The report is sent to the surgeon for approval.

Final Approval:
The physician must provide written approval of the plate design prior to manufacturing.
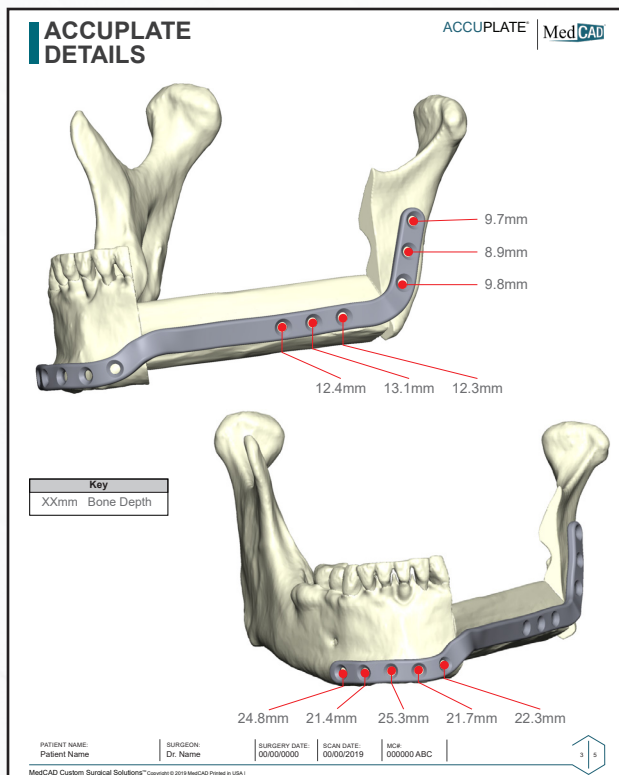
4. MANUFACTURE

Once plate design is approved, the patient-specific implant is manufactured. The MedCAD AccuPlate Patient-Specific Plates are intended to be designed and manufactured from commercially pure titanium at a MedCAD manufacturing facility.

Patient-specific plates are CNC milled for structural integrity.

5. SHIP

Implant is shipped <u>non-sterile</u>.

ACCUPLATE DETAILS

ACCUPLATE | MedCAD

9.7mm
8.9mm
9.8mm

12.4mm   13.1mm   12.3mm

Key
XXmm   Bone Depth

24.8mm   21.4mm   25.3mm   21.7mm   22.3mm

PATIENT NAME: Patient Name
SURGEON: Dr. Name
SURGERY DATE: 00/00/0000
SCAN DATE: 00/00/2019
MC#: 000000 ABC
3 | 5

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PREPARE THE IMPLANT AND ANATOMY
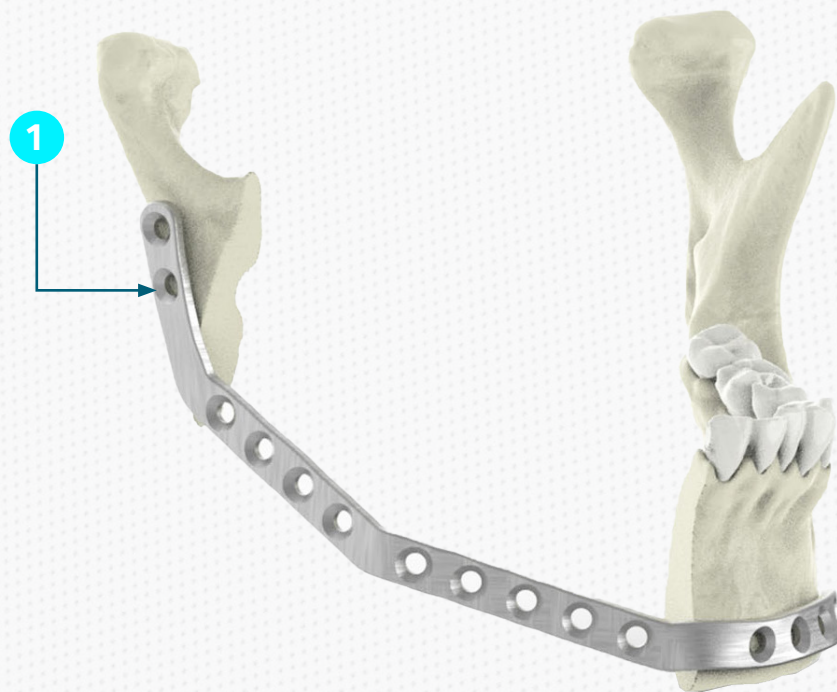
6. STERILIZATION

Implant is provided non-sterile and must be sterilized prior to use. Please refer to the Instructions For Use (IFU) for more information on sterilization.

7. EXPOSE AND REDUCE MANDIBLE

After completing the preoperative plan, expose and reduce the mandible segments as necessary. For the techniques described below, regardless of the options chosen, drill the hole closest to the fracture or osteotomy site in the proximal (posterior) segment ❶.

8. PLACEMENT

Place the plate over the fracture or resection site as indicated within the Case Report.

9. DRILLING

Drill the hole closest to the fracture or osteotomy site in the distal (anterior) segment ❷. Pre-drill based on information in the case report.

10. INSERT SCREW

Determine the appropriate screws to be used as indicated within the case report. Insert the proper length locking or non-locking screw through the plate and into the hole closest to the fracture or planned osteotomy site in the proximal segment ❶. Tighten the screw until secured.

Insert the second screw on the opposite side of the planned resection or fracture following the previously described procedure ❷.
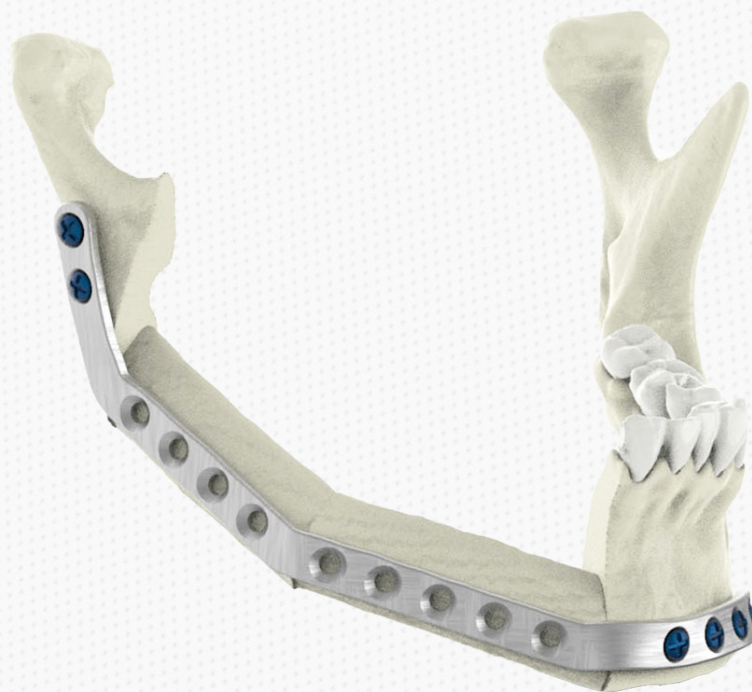

CAUTION:

Drill rates exceeding 1800 RPM may result in thermal necrosis of the bone and an oversized hole. The detriments of an oversized hole include reduced pullout force, increased ease of the screws stripping the bone, and/or suboptimal fixation.
Always irrigate while drilling. Avoid placing plate holes, drilling pilot holes or inserting screws over nerves and teeth roots.

PREPARE THE BONE GRAFT

11. APPLY BONE GRAFT

A vascularized or non-vascularized bone graft may be applied for a primary reconstruction. The patient specific plate may bridge continuity defects without a bone graft temporarily, prior to a secondary reconstruction.

NOTE: Stable fixation requires a minimum of two (2) screws per segment. When using reconstruction plates as a bridging device, allow for four (4) locking screws per segment.

CAUTION:

Plate fracture is possible when any plate bears the entire functional load for extended periods. Therefore, the implantation of a bone graft immediately or at a later date, is necessary to support the construct.

12. DRILL AND PLACE REMAINING SCREWS

Pre-drill and insert all remaining screws, alternating to each side of the resection or fracture. Securely tighten all screws. Apply additional fixation as desired.

CAUTION:

In order to achieve its planned outcome, AccuPlate is not intended to be bent or contoured. If for any reason AccuPlate does not match the treatment plan, generic off-the-shelf plating systems should be used.

HELPING YOU DO YOUR BEST WORK

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This document is intended for physicians and healthcare professionals. Surgeons must always rely on their clinical judgement and use discretion when selecting products to use with an individual patient. MedCAD does not offer clinical advice and recommends that all surgeons are trained prior to use of any product in surgery. Always refer to the instructions for use, package inserts, and labels, including sterilization instructions, before using MedCAD products.

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CUSTOM SURGICAL SOLUTIONS