

### INSTRUCTIONS FOR USE

#### CAUTION

- **R<sub>x</sub> ONLY.** FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

#### WARNING

- MedCAD AccuPlan® patient-specific dental splints are supplied **NON-STERILE**. MedCAD AccuPlan® patient-specific dental splints may be processed according to the instructions provided herein.

#### DESCRIPTION:

MedCAD AccuPlan® patient-specific dental splints provide surgeons temporary occlusal guides. The splints are designed to fit the individual anatomy of a specific patient. The splints are supplied **NON-STERILE**.

#### INDICATIONS:

MedCAD AccuPlan® patient-specific splints and wafers are temporary non-implantable guides designed individually for each patient and intended to assist surgeons during surgery to align the maxilla and/or mandible. They are used intraorally during surgical treatment to guide surgical processes.

#### CONTRAINDICATIONS:

- **DO NOT USE** in cases where active infection is present.

#### STORAGE:

Packaged products should be stored in a dry, clean environment, protected from direct sunlight, pests and extremes of temperature and humidity.

#### PROCESSING:

The following method may be used to process parts:

- Remove product from packaging and double wrap parts using a Kinguard® Sterilization Wrap, or equivalent.
- Do not place any objects on top of device during autoclave cycle or during cool down time.

Method	Temperature °C (°F)	Cycle Time	Cool Down Time
Dynamic-Air-Removal Steam Autoclave (1 Cycle)	132 °C (270 °F)	4 Minutes	60 Minutes  <i>Do not unwrap until ready for use.</i>