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INSTRUCTIONS FOR USE

CAUTION: R_x ONLY. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

PATIENT SPECIFIC DEVICE: MedCAD AccuPlan[®] splints

WARNINGS:

MedCAD AccuPlan[®] patient-specific dental splints are supplied **NON-STERILE** and must be sterilized prior to use according to the sterilization 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.

DO NOT USE in edentulous cases.

STORAGE:

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

STERILIZATION INSTRUCTIONS:

Remove from package and use one of the following steps to sterilize splint components.

Method	Temperature °C (°F)	Minimum Cycle Time (minutes)
Sterrad (Hydrogen Peroxide)	45-50 °C (113 °F-122 °F)	45 minutes
Steris	50-56 °C (122 °F -133 °F)	12 minutes
Cidex [®] OPA	Room temperature	12 minutes
Gluteraldehyde (Cidex Plus [®] and Cidex [®])	Room temperature	20 minutes