

## GUIDE™

Bio-Compatible Dental Model Resin



## STERILISATION VALIDATION PROCEDURES

GUIDE Bio-Compatible resin is for 3D-printed medical appliance for individual patients. It is used exclusively for intra-oral, guided dental implant procedures by certified dental professionals. Sterilisation via steam is required before use, as detailed below.

### PRE-STERILISATION STEPS

#### 1. Cleaning

Remove visible contaminants from the surface using alcohol. Ensure that no visible impurities are left and that the surface feels smooth to touch.

#### 2. Drying

Dry the item, particularly in complex geometries. Compressed air is acceptable for this step.

#### 3. Inspection

After drying, inspect for damages or cracks. Replace if necessary.

#### 4. Packaging

Use sterilisation pouches that meet DIN EN ISO 11607/ANSI/AAMI ST79/AAMI TIR12:2010 standards. Follow packaging guidelines from the manufacturer and ensure that the seal is free from defects.

### STERILISATION PARAMETERS

**Steriliser Type:** Prevacuum

**Pulses:** 4

**Temperature:** 134°C

**Full Cycle Time:** 4 minutes

**Dry Time:** 20 minutes

**Configuration:** Double pouches, 140mm x 330mm and 190mm x 330mm

STERILISATION  
PROCEDURES

### Post-Sterilisation

Allow devices to cool undisturbed.

Minimum drying time post sterilisation is 30 minutes; longer may be necessary depending on various factors.

### Storage

Store the sterilised product at room temperature (18–25°C), in a dry place, within the sterile bag's time limit.

### Warnings

Do not re-sterilise

Single-use only

