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**Custom Made Device**  
for the exclusive use of this patient.

Date: ..... Case No. ....

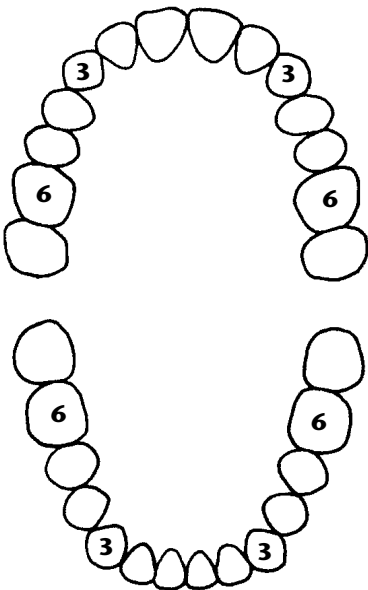
Study Models ☐ U ☐ L Work Models ☐ U ☐ L Digital Models ☐ U ☐ L Bite ☐

LABORATORY USE ONLY

**RIGHT**

**LEFT**

**CASE INSTRUCTIONS:**



**Patient's Name:** .....

**Doctor's Name:** .....

**Practice/Clinic:** .....

Private ☐ H.S.E. ☐ Date/Time of completion: ..... Final Inspection: .....

### STATEMENT

The device(s) conforms to the relevant essential requirements set out in Annex 1 of the Medical Devices Directive (93/42/EEC), S.I. No.252 of 1994. Those relevant essential requirements not met and reasons why are listed on the attached sheet (tick if appropriate ☐).

**THIS DEVICE IS SUPPLIED IN A NON-STERILE STATE - KEEP AWAY FROM EXTREMES OF HEAT AND COLD**