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## **Guide / model sterility and biocompatibility**

### **Biocompatibility**

All items anticipated to be in contact with the patient's tissues, or from which particulate debris might be created, are printed in material rated by as Class 1 biocompatible (EN-ISO 10993-1:2009/AC:2010, USP Class VI) by the 3D-printer manufacturer. These items include osteotomy guides, reduction guides, and drill guides.

Class 1 biocompatibility implies an absence of cytotoxicity, sensitization, tissue irritation, acute systemic toxicity and genotoxicity.

All other items are printed in non-biocompatible plastic (unless specified; note that any item can be printed in any plastic, although biocompatible plastic is significantly more expensive). These items usually include 3D-bone and vertebral models.

### **Sterility**

All 3D-printed items are supplied non-sterile.

Autoclave guidelines are as follows –

- Osteotomy, reduction and drill guides
  - Orange translucent plastic
  - Autoclavable - recommend protocols are below, however all standard protocols are acceptable.
    - 138°C for 3 minutes
    - 134°C for 6 minutes
    - 121°C for 15 minutes
- Pre-operative bone models
  - Yellow translucent plastic
  - Autoclavable - recommend protocols are below, however all standard protocols are acceptable.
    - 138°C for 3 minutes
    - 134°C for 6 minutes
    - 121°C for 15 minutes
- Post-operative bone models
  - White plastic.
  - Non-autoclavable – may survive an autoclave cycle but some models will split, flake or deform.
- Clear plastic models
  - Non-autoclavable.