CBM MEDICAL_ Sterilisation Policy

All CBM devices and products are delivered **NON-STERILE.**

It is the client's responsibility to ensure sterilisation and validation of sterilisation equipment. Models, guides and/or implants are provided in sealed packaging to prevent deterioration of cleanliness and minimise the risk of microbial contamination.

If the client has any questions regarding the materials, handling, storage, cleaning and sterilisation please contact CBM directly.

ANATOMICAL MODELS

The anatomical models are delivered **NON-STERILE.**

For the ISO 10993 and USP 23 Class VI approved materials, Autoclaving, is an appropriate sterilisation method, a standard cycle at 134-137 °C, with a drying cycle of 30 mins (**Please be aware** that model thin wall sections, 1.5mm or less may distort during autoclaving, but thicker sections are more likely to withstand the process).

Alternative sterilisation methods that will not affect the dimensional accuracy include: Formaldehyde at 80°C, Low temperature steam at 75°C and Gamma radiation.

Do not use the models if the package was opened or damaged during delivery. It is recommended to only open the package immediately before preparing the model for surgery (i.e. before sterilisation).

If the model is opened and handled prior to sterilising, or altered (rehearse of surgical procedure) CBM can accept no responsibility for the cleanliness and suitability for sterilising.

SURGICAL IMPLANTS

The surgical implants are delivered **NON-STERILE.**

Autoclaving is an appropriate sterilisation method for the implants, a standard cycle at 134-137 °C, with a drying cycle of 30 mins. Do not use the implants if the package was opened or damaged during delivery. Only open the package immediately before preparing the implants for surgery (i.e. before sterilisation).

SURGICAL GUIDES

The surgical guides are delivered **NON-STERILE.**

Autoclaving is an appropriate sterilisation method for the guides, a standard cycle at 134-137 °C, with a drying cycle of 30 mins. Do not use the guides if the package was opened or damaged during delivery. Only open the package immediately before preparing the guides for surgery (i.e. before sterilisation).

MARKINGS:

- Markings on the models, guides and/or implants are used for indicating anatomical references and case information must be legible. These include lines indicating anatomical directions, identifiers with case information such as implant size and unique case identifiers.

- A unique **CBM identifier code** is indicated on each model, guide and/or implant. This code links the product unambiguously to the patient case. A list of the unique identifier codes is present in the case report shipped with each client case.

- Before using the model, guide and/or implant, check the unique identifier for readability and confirm that it corresponds with the patient's identity.

WARNINGS:

- Models, guides and/or implants should ideally be stored in a cool, dry place out of direct sunlight.
- Do not apply excessive force on the models or place heavy objects on top.
- Do not use the guides and/or implants if they are broken, cracked, or visibly contaminated.
- Before the products are sterilised, carefully examine them to see if they are clean and undamaged.
- The models, guides and implants must be sterilised prior to use in surgery.
- These are custom patient specific, single use, disposable models and guides.
- Do not attempt to reuse the models or guides.
- It is advised to use the model, guides and/or implants within 6 months after performing the CT/ MRI scans which they are based. If the patient's anatomy has changed significantly since the time of the scan, the model, guides and/or implants should not be used, even if the time period of 6 months is not expired.
- CBM can accept no liability for the results of treatments undertaken using the models, guides and/or implants. The accuracy of the products should be checked before use.