INSTRUCTIONS FOR USE (IFU)

MCI CMF Instruments

1. PRODUCT IDENTIFICATION

Trade Name: MCI CMF Instruments
Type: Surgical Instruments for Craniomaxillofacial
Condition: Supplied Non-Sterile – Reusable Medical Device

2. INTENDED USE

MCI CMF Instruments are intended to assist surgeons during craniomaxillofacial surgical procedures involving the fixation of bone using compatible plates and screws from the MCI CMF System.
These instruments are used for:

- Drilling, measuring, holding, cutting, bending, and inserting implants
- Assisting in placement and fixation of CMF implants

3. INDICATIONS FOR USE

The instruments are indicated for use in surgical procedures involving:

- Cranio-maxillofacial trauma fixation
- Orthognathic surgery
- Reconstruction of facial bones

They are designed to be used in conjunction with MCI CMF implants (1.5 mm and 2.0 mm systems)

4. INTENDED USERS

- Qualified surgeons
- Trained healthcare professionals in clinical/hospital environments

5. DEVICE DESCRIPTION

The MCI CMF Instrument Set includes reusable surgical instruments such as:

- Screwdrivers and handles
- Drill guides and drills
- Plate benders and cutters
- Forceps and holding devices
- Depth gauges and transbuccal instruments

These instruments are designed to interface with MCI CMF and trays
Materials typically include stainless steel and other medical-grade alloys suitable for repeated sterilization.

6. CONTRAINDICATIONS

- Do not use instruments for purposes other than intended surgical procedures
- Do not use damaged, worn, or malfunctioning instruments
- Do not use instruments without proper sterilization

7. WARNINGS

- Instruments must be used only by trained professionals
- Improper use may lead to surgical complications or implant failure
- Excessive force may damage instruments or implants
- Inspect instruments before each use; replace if:
    - Loss of function
    - Corrosion or deformation
    - Reduced cutting or gripping performance
- Compatibility with non-MCI implants must be evaluated by the user

8. PRECAUTIONS

- Use appropriate instrument for each surgical step
- Avoid dropping or mechanical shock
- Keep instruments clean and dry when not in use
- Do not expose to corrosive chemicals
- Follow validated cleaning and sterilization procedures

9. REPROCESSING INSTRUCTIONS (REUSABLE DEVICE)

9.1 General Principles

Instruments must be **cleaned, disinfected, and sterilized before each use**.

9.2 Cleaning Procedure

Immediately After Use

- Remove gross contamination
- Prevent drying of blood/tissue

Manual Cleaning

1. Disassemble (if applicable)
2. Immerse in enzymatic detergent (room temperature)
3. Brush with soft bristle brush
4. Rinse thoroughly with clean water

⚠ Do not use:

- Metal brushes
- Abrasive materials
- Strong acids or corrosive agents

9.3 Automated Cleaning (Optional)

- Follow washer-disinfector manufacturer instructions
- Ensure instruments are open/disassembled

9.4 Disinfection

- Use approved disinfectant solution
- Follow validated time, concentration, and temperature

9.5 Rinsing

- Use purified or deionized water
- Ensure complete removal of residues

9.6 Drying

- Use lint-free cloth or medical-grade drying system
- Ensure complete drying, including joints and lumens

9.7 Inspection

Before sterilization, verify:

- Cleanliness
- Integrity
- Functionality (movement, alignment, cutting edges)

10. STERILIZATION

Recommended Method: Steam Sterilization (Autoclave)

Validated typical cycle:

- Temperature: **134°C**
- Exposure Time: **≥ 7 minutes**
- Drying Time: **≥ 15 minutes**

Sterilization must comply with:

- ISO 17665-1
- ISO 17665-2

⚠ Healthcare facility is responsible for:

- Validation of sterilization process
- Load configuration

11. STORAGE CONDITIONS

- Store in a clean, dry environment
- Protect from:

- Humidity
- Dust
- Direct sunlight

12. TRANSPORT AND HANDLING

- Transport in protective packaging or trays
- Avoid impacts or mechanical damage
- Segregate damaged instruments

13. USEFUL LIFE

Reusable instruments may be used multiple times provided they:

- Pass inspection
- Maintain functionality and integrity

Discard if:

- Corroded
- Deformed
- Functionally compromised

14. DISPOSAL

- Dispose according to local regulations for medical devices
- Damaged instruments should be physically destroyed before disposal

15. COMPLAINTS AND REPORTING

Any serious incident or malfunction must be reported to:

- MCI – Medical Concept Innovation
- Applicable regulatory authorities

16. MANUFACTURER

MCI – Medical Concept Innovation
4592 North Hiatus Road
Sunrise, FL 33351 – USA
Phone: +1 954 306 2521
Email: customer.service@mci-medical.com

17. SYMBOLS AND LABELING

Refer to product labeling for:

- Non-sterile symbol
- Reusable device symbol
- Manufacturer information
- Batch/lot traceability