

## INSTRUCTIONS FOR USE (IFU)

### MCI Neuro Instruments

#### 1. PRODUCT IDENTIFICATION

**Trade Name:** MCI Neuro Instruments

**Type:** Surgical Instruments for Cranial and Neurosurgical Procedures

**Condition:** Supplied Non-Sterile – Reusable Medical Device

#### 2. INTENDED USE

MCI Neuro Instruments are intended to assist surgeons during neurosurgical procedures involving cranial bone fixation, including the placement and removal of neuro fixation implants (plates, meshes, and screws).

#### 3. INDICATIONS FOR USE

The instruments are indicated for use in surgical procedures involving:

- Cranial fixation following craniotomy
- Stabilization of cranial bone flaps
- Cranial reconstruction procedures

#### 4. INTENDED USERS

- Neurosurgeons
- Trained healthcare professionals in clinical or hospital settings

#### 5. DEVICE DESCRIPTION

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

- Screwdrivers and handles
- Drill bits and drill guides
- Depth gauges
- Plate benders and cutters
- Holding forceps and positioning tools

These instruments are designed for use with MCI Neuro Fixation Systems and compatible cranial implants.

#### 6. CONTRAINDICATIONS

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

## 7. WARNINGS

- Use only by trained neurosurgical professionals
- Improper use may result in:
  - Dural perforation
  - Cerebrospinal fluid (CSF) leakage
  - Intracranial injury or bleeding
- Excessive force or improper drilling depth may damage bone or underlying structures
- Always verify instrument integrity before use
- Replace instruments showing wear, deformation, or loss of performance
- Compatibility with non-MCI implants must be evaluated by the user

## 8. PRECAUTIONS

- Use depth-controlled drilling techniques when applicable
- Avoid excessive pressure during drilling or fixation
- Maintain clear visualization of the surgical site at all times
- Do not use instruments for unintended purposes
- Protect instruments from mechanical damage and corrosion

## 9. REPROCESSING INSTRUCTIONS (REUSABLE DEVICE)

### 9.1 General Requirements

All instruments must be cleaned, disinfected, and sterilized before each use.

### 9.2 Cleaning

#### Immediately After Use

- Remove gross contamination
- Prevent drying of biological material

#### Manual Cleaning

1. Disassemble instruments (if applicable)
2. Immerse in enzymatic detergent solution (room temperature)
3. Clean using soft brushes, paying attention to joints and lumens
4. Rinse thoroughly with clean water

#### ⚠ Do not use:

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

### 9.3 Automated Cleaning

- Use validated washer-disinfector cycles
- Ensure instruments are opened or disassembled

#### 9.4 Disinfection

- Use approved disinfectants according to manufacturer instructions
- Follow validated exposure times and concentrations

#### 9.5 Rinsing

- Use purified or deionized water
- Ensure complete removal of cleaning agents

#### 9.6 Drying

- Use lint-free cloth or medical drying systems
- Ensure complete drying, especially in joints and cavities

#### 9.7 Inspection

Before sterilization, verify:

- Cleanliness
- Mechanical integrity
- Proper function (movement, cutting, gripping)

### 10. STERILIZATION

#### Recommended Method: Steam Sterilization (Autoclave)

Typical validated parameters:

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

Sterilization must comply with:

- ISO 17665-1
- ISO 17665-2

⚠ The healthcare facility is responsible for validating sterilization processes.

### 11. STORAGE CONDITIONS

- Store in a clean, dry environment
- Protect from humidity, contamination, and direct light

### 12. TRANSPORT AND HANDLING

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

### 13. USEFUL LIFE

Reusable instruments may be used multiple times provided they:

- Pass inspection
- Maintain functionality and structural integrity

Discard if:

- Corrosion
- Deformation
- Loss of function

### 14. DISPOSAL

Dispose of instruments in accordance with local regulations for medical devices.  
Damaged instruments should be physically destroyed before disposal.

### 15. COMPLAINTS AND VIGILANCE

Any serious incident 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](mailto: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

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