Technical and clinical information

Technical Guideline

MONDE|neuro
Flexible Plating Systems for Neuro-Surgery

NEURO Create-Quick
NEURO Flexible Plating System

Systems for Neuro-Surgery
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The Cranio-Quick sets contain selected plates and screws for special cranial indications:

- Self-drilling screws
- Miniaturized plates
- Double sterile packaging

NEURO Flexible Plating System
This user-friendly osteosynthesis system was developed in order to cover common areas of the cranium.

- Cranio-facial surgery
- Fixation of bone grafts
- Reconstructive neuro-surgery
- Skull fractures / skullbase fractures
Implants | Screws

Features & Advantages

- Screw head-design „self-retaining”
  - Safe self-retaining mechanism of screw and screwdriver blade
  - Easy and simple removal of screw
  - Different connection types:
    - CF (CROSS-FIT)
    - MCD (Mondeal Contour Drive)

- Screw thread „self-tapping”
  - Optimal self-tapping ability thanks to sharp and precise thread
  - Stable fixation in the bone

- Screw tip „atraumatic”
  - Atraumatic screw tip avoids impairments and irritations of the soft tissue
  - Gently for patient

- Screw tip „self-drilling”
  - Self-drilling screw for skullcap
  - No pre-drilling necessary

Note from General IFU

*Self-drilling screws are not recommended in very small, thin and loosened bone fragments because the fragments may be displaced by the axial pressure of insertion.*

Benefits of titanium for implants

In general, pure titanium (DIN EN ISO 5832-2/ASTM F67) is used for the manufacturing of bone plates while the titanium alloy (DIN EN ISO 5832-2/ASTM F136) is used for the manufacturing of bone screws. Worldwide, these materials are used for short and long-term implants in the osteosynthesis for decades.

For the following reasons:
- Completely biocompatible
- Corrosion-resistant
- Non-toxic in the biological environment
- Failure-free imaging with X-rays, computed tomography (CT) and magnetic resonance imaging (MRI)
Implants | Plates

Thickness 0.6 mm

Plates straight with / without bar

CAD Plates

Double-Y-Plate

Neuro Gap Plate
Sizes S / M / L

Burr Hole Cover Plates
with / without side-drainage

Optionally available with tag

All plates with tag are laser marked with company name, Art. No and LOT No
**Instruments for screws | Screw-receiving and fixation**

**Screw-receiving out of the tray with self-retaining blade**

Insert screwdriver blade into the screw head and press firmly. Remove the screw vertically.

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**Note from General IFU: Connection screwdriver and screw head**

- It is essential to ensure that the screwdriver/screw head connection is aligned exactly in the vertical direction; otherwise, there is an increased risk of mechanical damage to the implant or the screwdriver.

- When engaging the bone screw, axial pressure of the screwdriver into the screw head must be adequately applied to ensure that the blade is fully inserted into the screw head. This results in axial alignment and full contact between screwdriver and screw.
Instruments for screws | *Screw-receiving and fixation*

**Screwdriver handle**
- Length 9 cm

**Blade, self-retaining**

Assembly of blade (self-retaining) and screwdriver handle:

1. [Image of assembly step 1]
2. [Image of assembly step 2]
3. [Image of assembly step 3]
4. [Image of assembly step 4]
Instruments for screws | **Drilling**

**Drill**

<table>
<thead>
<tr>
<th>Diam. x Length</th>
<th>Working length</th>
<th>Connection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.4 x 46 mm</td>
<td>5 mm</td>
<td>Stryker</td>
</tr>
</tbody>
</table>

**Notes from General IFU: Drills**

- *Small Drills are recommended for single use only. Damage is difficult to detect due to the small dimensions.*
- *Drills are provided with depth stops to prevent accidental penetration beyond the targeted bone.*
- *A drilling speed of 500-800 rpm must be maintained to avoid overheating and bone necrosis. When using high speed power sources, the user must verify with the manufacturer a setting that corresponds to a maximum speed of 800 rpm.*
- *When using twist drills, it is essential to provide adequate cooling by means of copious normal saline irrigation (NaCl) to minimize thermal damage to the bone tissue. The combination of cooling and low speed (<800 rpm) significantly contribute to the reduction of screw loosening due to bone de-mineralization.*
- *Twist drills are developed and indicated for work at low speeds (<800 rpm). Higher rates of rotations may result in failure of the drill and potential injury to the user, patient or third parties.*
- *Axial guidance of the drill considerably reduces the risk of breakage and wear.*
- *Always use the shortest drill possible given the clinical indication. Longer drills are naturally susceptible to more eccentric rotation, especially when operated in air, free of resistance.*
- *The user must verify the compatibility of the drill with the attachment hand piece. In addition, regular maintenance and inspection of the hand piece are essential to prevent damage to the drill.*
Titanium MESH

Flexible Mesh
Thickness: 0.6 mm

Micro Mesh
Thickness: 0.1 mm and 0.2 mm

Hexagonal Mesh
Thickness: 0.6 mm

- The MESH bending pliers enables to shape all types of mesh in certain radii gently and precisely in a simple manner.
- You can choose between two preforms (M-preform and L-preform) with varying radii, which can be changed as needed.
- The use of the MESH bending pliers saves time and prevents buckling of the material during molding.

Using the MESH cutter, the mesh can be cut to the desired size and shape.

Preforms
convex
concave

MESH bending pliers

MESH cutter
Container

Tray for

- Implants (Screws, plates)
- Instruments
Cranio-Quick sterile sets

These products are supplied in double pre-sterilized packaging.

Thickness: 0.6 mm

Screws Ø 1.7 mm
Length 4 mm
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