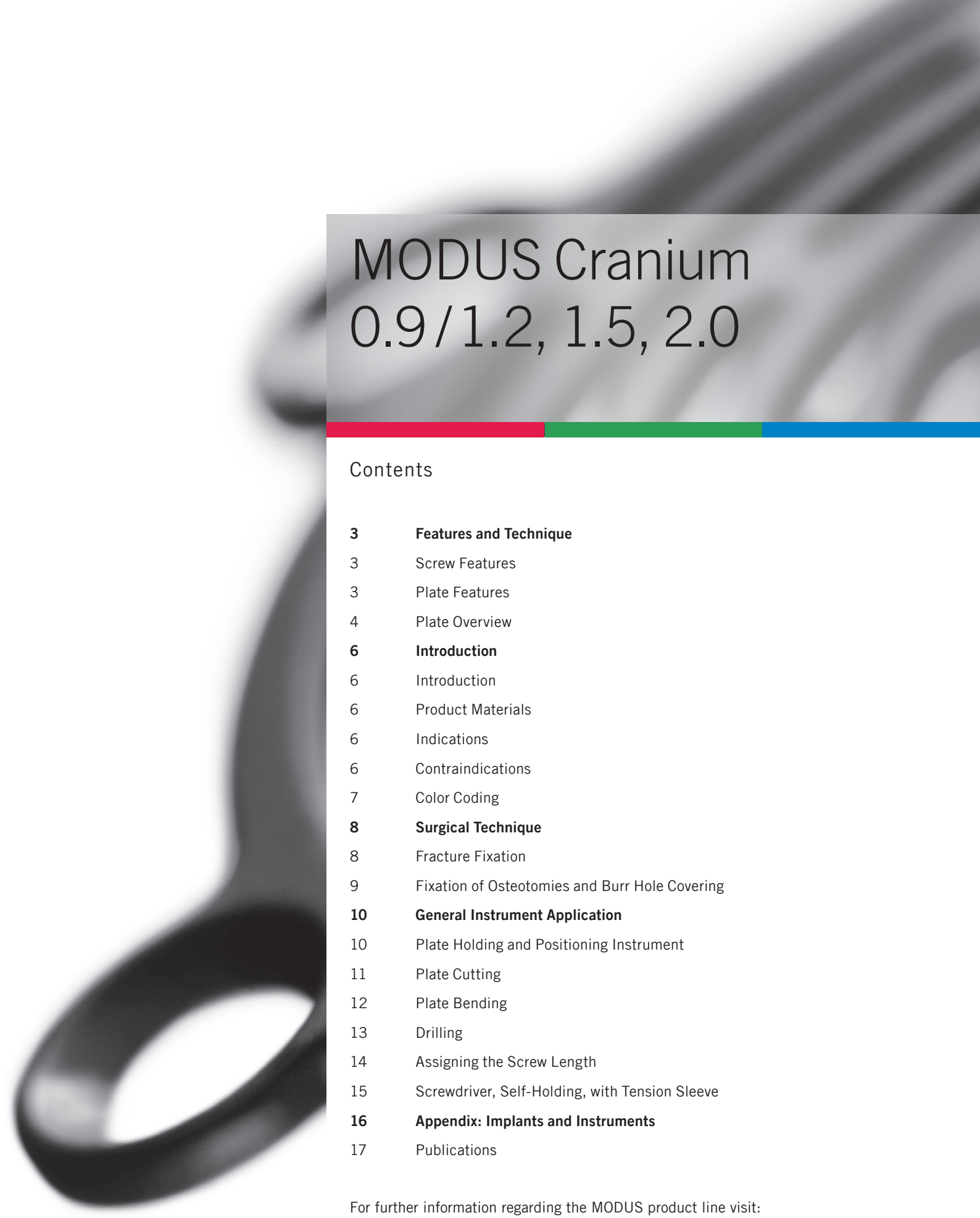
medartis®

PRECISION IN FIXATION

SURGICAL TECHNIQUE – STEP BY STEP

Cranium 0.9/1.2, 1.5, 2.0

MODUS® Cranium



MODUS Cranium 0.9/1.2, 1.5, 2.0

Contents

For further information regarding the MODUS product line visit:
www.medartis.com/products

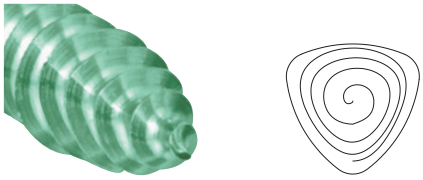
Features and Technique

Screw Features

- Self-tapping screws with precise and sharp thread
- HexaDrive interface with patented self-holding properties
- SpeedTip thread design for screw insertion without pre-drilling

SpeedTip Thread Technology

- Immediate cutting of the bone with only a slight axial pressure
- The triangular tip design permits simultaneous drilling, intrusion and compression of the bone tissue during insertion for increased pull-out stability[1,2]
- Reduced insertion torque thanks to the polygonal tip and tapered shaft



Caution: When using self-drilling screws, no pre-drilling is required. If the insertion torque resistance is disproportionately high, appropriate pre-drilling is always recommended.

HexaDrive Technology

- HexaDrive screw head design
  - Secure connection between screw and screwdriver
  - Increased torque transmission
  - Simplified screw pick-up due to patented self-holding technology

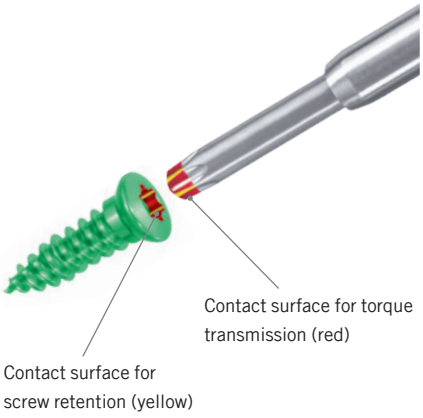


Plate Features

- Low overall profile height
- Chamfered plate contour offering protection of the soft tissue
- Bending and cutting for a wide range of applications

Plate Overview

Generic Cranial Plates

Generic cranial plates are designed for internal fixation of fractures and osteotomies. According to the respective MODUS system size, generic cranial plates are available in different variants, covering plate size, thickness and rigidity. Within a particular MODUS system size, different design variants (e.g. bar length, number of holes) of generic cranial plates are available.
For the complete plate survey, please refer to the MODUS ordering catalog, also available at www.medartis.com.

Description	Examples	Plate thickness	Rigidity	System
Straight plates	 M-4102	0.5 mm	rigid	0.9/1.2
	 M-4224	0.6 mm	rigid	1.5
T, Y, double Y plates	 M-4134	0.5 mm	rigid	0.9/1.2
	 M-4242	0.6 mm	rigid	1.5
L plates	 M-4238	0.6 mm	rigid	1.5
Grid plates	 M-4186	0.5 mm	rigid	0.9/1.2
	 M-4283	0.7 mm	semi-rigid	1.5

→ www.medartis.com/products/modus

Burr Hole Cover Plates

Burr hole cover plates are specifically designed for cranial closure procedures (burr hole covering; flap closure following craniotomies).

Art. No.	Examples	Plate thickness	Plate diameter	System
M-4156		0.5 mm	15 mm	0.9/1.2
M-4158		0.5 mm	23 mm	0.9/1.2
M-4262		0.6 mm	16 mm	1.5
M-4290		0.6 mm	22 mm	1.5
M-4264		0.6 mm	24 mm	1.5
M-4348		1.0 mm	17 mm	2.0
M-4350		1.0 mm	25 mm	2.0

Introduction

Introduction

Medartis develops, manufactures and sells titanium screws and plates, surgical instruments and system solutions for fracture fixation. These implants allow for patient rehabilitation after surgical reconstruction of fractures, malunions and deformities or skeletal diseases and their adjacent soft tissues. Our motto is «Precision in fixation». We place the highest priority on maintaining stringent quality standards, continuous further development and innovation as well as comprehensive service provision for surgeons, staff and patients.

MODUS is a complete modular system for the fixation of fractures, corrective osteotomies, bridging of load-bearing bone segments, and reconstructive procedures to the facial skeleton (skullcap, midface, and jaw). All MODUS implants are characterized by an extremely low plate profile, resulting in cosmetically appealing results with optimal stability. Featuring an innovative range of plates and screws in various dimensions, anatomical forms and geometries, MODUS comprises systems for a variety of indications. MODUS Cranium offers solutions for craniotomies and cranial trauma repair.

Product Materials

All MODUS implants are made from pure titanium (ASTM F67, ISO 5832-2) or from titanium alloy (ASTM F136, ISO 5832-3). All of the titanium material used is biocompatible, corrosion-resistant and non-toxic in a biological environment. The instruments are made of stainless steel, PEEK, aluminum or titanium.

Indications

The MODUS Cranium plate and screw system is used for fixation of fractures, osteotomies and reconstructive procedures that require postitional and functional stability in the upper midface and skullcap.

Contraindications

- Pre-existing or suspected infections at or near the implantation site
- Known allergies and/or hypersensitivity to implant materials
- Inferior or insufficient bone quality to securely anchor the implant
- Patients who are incapacitated and/or uncooperative during the treatment phase
- Blocking of cranial sutures/growth plates with plates and screws
- Not intended for use in direct contact with the dura mater and the central nervous system

Color Coding

The different MODUS plate and screw system sizes are indicated by a system-specific color code.

System	Color Code
MODUS 0.9/1.2	Red
MODUS 1.5	Green
MODUS 2.0	Blue
MODUS Mesh	Yellow

Plates and Screws

The implant colors indicate the characteristics of the implant:

Implant plates gold	Rigid fixation plates
Implant plates green	Semi-rigid fixation plates
Implant plates blue	Semi-rigid fixation plates
Implant screws gold	Cortical screws (fixation)
Implant screws green	SpeedTip screws (self-drilling)

Symbols


HexaDrive


Cross-drive


Self-drilling screw

Instruments

The instruments belonging to a specific system size are color-coded accordingly.
Instruments that do not belong to a particular system do not have a color code.

Options for Plate and Screw Combinations

Plates and screws can be combined within one system size:

0.9/1.2 Fixation plates

0.9 Cortical screws, cross-drive
1.2 Cortical screws, cross-drive

1.5 Fixation plates

1.5 Cortical screws, cross-drive
1.5 Cortical screws, HexaDrive 4
1.5 SpeedTip screws, cross-drive
1.5 SpeedTip screws, HexaDrive 4
1.5 Cortical screws, self-drilling, cross-drive
1.8 Cortical screws, cross-drive (Emergency)
1.8 Cortical screws, HexaDrive 4 (Emergency)

2.0 Fixation plates

2.0 Cortical screws, cross-drive
2.0 Cortical screws, HexaDrive 6
2.0 SpeedTip screws, cross-drive
2.0 SpeedTip screws, HexaDrive 6
2.3 Cortical screws, cross-drive (Emergency)
2.3 Cortical screws, HexaDrive 6 (Emergency)

0.9/1.2 Mesh

0.9 Cortical screws, cross-drive
1.2 Cortical screws, cross-drive

1.5 Mesh

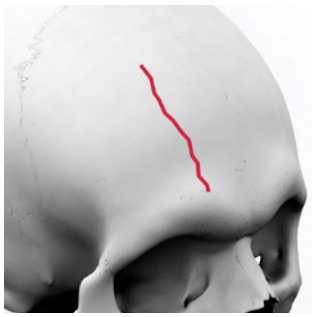
1.5 Cortical screws, cross-drive
1.5 Cortical screws, HexaDrive 4
1.5 SpeedTip screws, cross-drive
1.5 SpeedTip screws, HexaDrive 4
1.5 Cortical screws, self-drilling, cross-drive
1.8 Cortical screws, cross-drive (Emergency)
1.8 Cortical screws, HexaDrive 4 (Emergency)

Vario Mesh can be combined with any screw listed above.

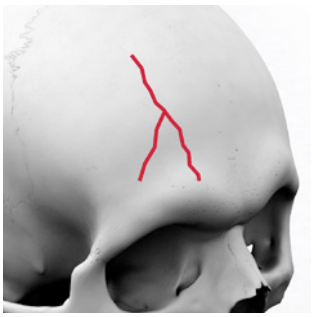
Surgical Technique

Fracture Fixation

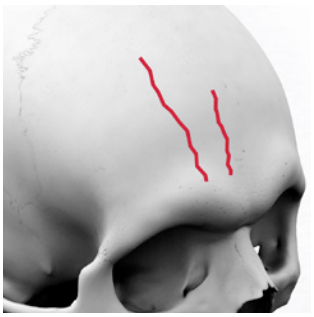
The majority of head traumas involve the cranial vault. Depicted are some examples of common cranial vault fractures:



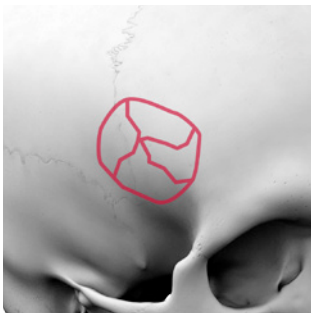
Single fracture line



Branched fracture lines



Multiple fracture lines



Comminuted fracture

1. Implant selection
According to requirements and indication, select the appropriate implants (plate design and thickness that suit best the treatment objective and the patient's anatomy).

2. Plate adaption (if required)
If required, use appropriate MODUS cutting and bending pliers to cut and contour the plate for optimized fit to the patient anatomy and to meet the needs of the specific case (for details on instrument handling, see section «General Instrument Application»).

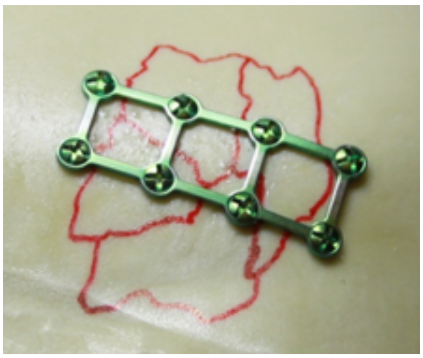
3. Plate positioning
Place the implant plate on the desired location over the fracture or the osteotomy site.

For secure handling and positioning of the implant plate, use the corresponding MODUS plate holding and positioning instrument (for details on instrument handling, see section «General Instrument Application»).

4. Pre-drilling of screw holes (optional)
Use the appropriate diameter drill bit for pre-drilling of screw holes.

Caution: Do not exceed a drilling speed of 1.000 revolutions per minute. Exceeding this speed can result in overheating of the bone and patient injury (bone necrosis).

5. Fixation of the implant plate to the bone
Stabilize the implant plate with screws using the appropriate screwdriver. Consider the size and shape of the fracture or osteotomy when determining the essential amount of fixation to achieve stability.



Notice:
Use the specified screwdriver for the particular implant system. Be sure that screwdriver and screw are aligned precisely. Improper alignment poses a risk of damage to the implant and the screwdriver blade.

6. Follow-up treatment and explantation of MODUS Cranium implants
In consideration of the individual fracture situation as well as patient's compliance, an adequate postoperative relief of the osteosynthesis in terms of adaption- or mobilization stability (e.g. splinting and/or immobilization) shall be ensured. Postoperatively, the fixation achieved by the implants must be treated carefully until osseous healing is completed. The doctor's aftercare instructions have to be strictly observed by the patient in order to avoid adverse loads of the implants. Early load bearing can increase the risk of loosening, migration or breakage of the devices.

For explantation of MODUS implants, use the appropriate screwdriver to remove the screw.

Caution: Please be aware, that only original MODUS instruments are recommended to be used for explantation.

Fixation of Osteotomies and Burr Hole Covering

1. Implant selection
According to requirements and indication, select the appropriate implants.

2. Plate adaption (if required)
If required, use MODUS modeling pliers to match the curvature of the bone (for details on instrument handling, see section «General Instrument Application»).

3. Plate positioning
Place the implant plate on the desired location over the burr hole or osteotomy site.

4. Pre-drilling of screw holes (optional)
For pre-drilling of screw holes, use the appropriate diameter drill bit.

Caution: Do not exceed a drilling speed of 1.000 revolutions per minute. Exceeding this speed can result in overheating of the bone and patient injury (bone necrosis).

5. Fixation of the implant plate to the bone
Stabilize the implant plate with screws using the appropriate screwdriver.

Tip for bone flap fixation
It may be advantageous to secure the implants to the bone flap first. Then position the bone flap and fix the plates on the skull.

Notice:
It is highly recommended to use at least three plates for fixation of osteotomies.

Notice:
Use the specified screwdriver for the particular implant system. Make sure that screwdriver and screw are precisely aligned. Improper alignment poses a risk of damage to the implant and the screwdriver blade.

6. Follow-up treatment and explantation of MODUS Cranium implants
In consideration of the individual fracture situation as well as patient's compliance, an adequate postoperative relief of the osteosynthesis in terms of adaption- or mobilization stability (e.g. splinting and/or immobilization) shall be ensured. Postoperatively, the fixation achieved by the implants must be treated carefully until osseous healing is completed. The doctor's aftercare instructions have to be strictly observed by the patient in order to avoid adverse loads of the implants. Early load bearing can increase the risk of loosening, migration or breakage of the devices.

For explantation of MODUS implants, use the appropriate screwdriver to remove the screw.

Notice:
Please be aware that only original MODUS instruments are recommended to use for explantation.

General Instrument Application

The instruments belonging to a specific system size are color-coded accordingly.
Instruments that do not belong to a particular system do not have a color code.

Plate Holding and Positioning Instrument

This multifunctional instrument can be used for handling of implant plates. The plate holding prongs are used to pick up and click-lock the implant plate, in order to remove it from the implant tray and transfer it to the operation site. The instrument ball tip facilitates the positioning, moving, and securing of the implant plate on the bone surface.

M-2171
M-2172
M-2173

Plate Cutting

If required, plates can be cut using multiple instruments:

Plate Cutting Pliers


M-2170


M-2140

Mesh Cutting Pliers


M-2870


M-2104

Vario Plate Cutting Pliers


M-2110

The Vario plate cutting pliers are designed to cut the MODUS implant plates individually. Position the implant plate over the pin with the appropriate color code. Insert the pin into the last plate hole that should remain on the implant plate. The pliers hold both sides of the plate after cutting, thereby preventing any scattering of fragments.

Tip:
To optimize the cut surfaces, turn the implant through 180° and cut the same hole again.

Notice:
Grid plates and mesh cannot be cut with this type of cutting pliers. For cutting of grid plates, use cutting pliers M-2170 and M-2140, respectively.
For cutting of mesh use cutting pliers M-2870 and M-2104, respectively.

→ www.medartis.com/products/modus

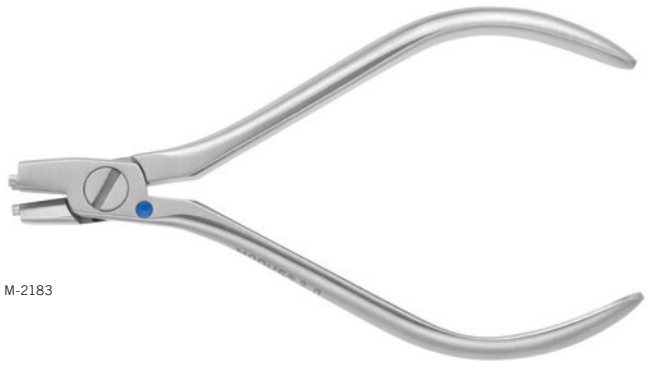
Plate Bending

If required, plates can be bent using multiple instruments.

Plate Bending Pliers, Three Prongs

M-2181

M-2182



M-2183

The three-pronged plate bending pliers have two pins on the upper jaw which fit exactly into the plate holes. As the jaws are closed, the plate bends in a curve along its side, while the plate holes are protected against deformation (1). To bend the plate on its flat surface, place it between the jaws of the pliers (2).

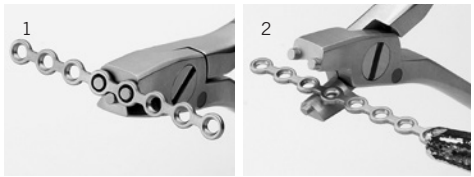


Plate Bending Pliers with Vario Pin

M-2150

The plate bending pliers with Vario pin can be used for simultaneous bending in multiple planes and are designed to protect the plate hole against deformation during the bending process.

Notice:
- The plate bending pliers with pin are always used in pairs
- Always place the Vario pin in the countersunk side of the plate hole

Notice:
- The plate must always be held at 2 adjacent holes to prevent contour deformation of the intermediate plate hole while bending.
- Do not bend the plate by more than 30°. Bending the plate further may deform the plate holes and may cause the plate to break postoperatively.
- Avoid repeatedly bending the plate in opposite directions, as this may cause the plate to break postoperatively.
- Always use the provided plate bending pliers to avoid damage to the plate holes. Damaged plate holes prevent correct and secure seating of the screw in the plate and increase the risk of system failure

Plate Bending Pliers, Flat Nose

M-2100

For simultaneous bending in multiple planes the plate bending pliers with flat nose can be used optionally.

Modelling Pliers for Plates and Mesh

M-2160

The modelling pliers (M-2160) can be used to model plates and mesh to match the curvature of the bone. By pressing the convex surface against the concave surface, the implant surface can be tailored without wrinkling the material. Exchangeable titanium inserts are available for the pliers in radius sizes of 15 mm (M-2540), 30 mm (M-2520) and 50 mm (M-2530).

Modelling mesh

Modelling plates

Modelling grid plates

Drilling

All twist drills are color-coded according to the system size to which they belong. The color and the number of rings indicate the size of the drill diameter.

System size 0.9/1.2

1 red ring	drill diameter 0.6 mm
2 red rings	drill diameter 0.7 mm
2 red rings + 1 yellow ring	drill diameter 0.75 mm
3 red rings	drill diameter 0.9 mm
4 red rings	drill diameter 1.0 mm

M-3221

M-3231

M-3301

M-3251

M-3341

System size 1.5

1 green ring	drill diameter 1.1 mm
2 green rings	drill diameter 1.2 mm
2 green rings + 1 yellow ring	drill diameter 1.25 mm
3 green rings	drill diameter 1.5 mm

M-3172

M-3112

M-3252

M-3142

System size 2.0

1 blue ring	drill diameter 1.5 mm
2 blue rings	drill diameter 1.6 mm
3 blue rings	drill diameter 2.0 mm

M-3173

M-3203

M-3143

Notice:
Twist drills are also available in different lengths, with different stops and with different shaft ends. For details, please see the MODUS ordering catalog.

Drill Stop Guide, Adjustable

The adjustable drill stop guide keeps the distal shaft of the twist drill straight to prevent it from vibrating or buckling during drilling. A fixation screw enables the stop depth to be set to any desired screw length.

Notice:

The drill stop guide can only be used with specifically designated twist drills. No other twist drills with a length stop will fit the drill guide.

M-2191 For use with twist drills M-3321, M-3311, M-3371 and M-3361 only.

M-2192 For use with twist drills M-3262, M-3252, M-3152 and M-3142 only.

M-2193 For use with twist drills M-3213, M-3203, M3243, M-3223, M-3153 and M-3143 only.

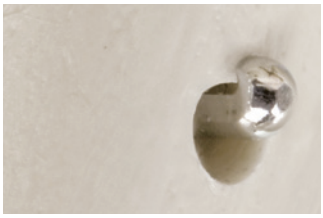
Assigning the Screw Length

The depth gauge is used to assign the ideal screw length for use in monocortical or bicortical screw fixation.

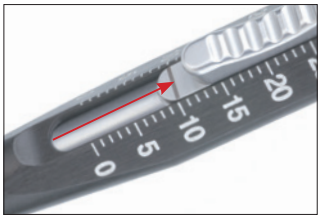
M-2250

M-2161

To assign the screw length, place the tip of the depth gauge onto the implant plate or directly onto the bone. The depth gauge caliper has a hooked tip that is either inserted to the bottom of the hole or is used to catch the far cortex of the bone. When using the depth gauge, the caliper stays static, only the slider is adjusted.



The ideal screw length for the assigned drill hole can be read on the scale of the depth gauge.



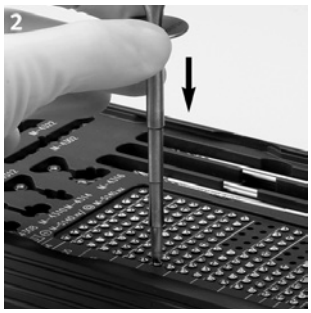
Screwdriver, Self-Holding, with Tension Sleeve

Screwdrivers are available with self-holding blades and with tension sleeves.

Screwdriver with tension sleeve: Removal of screws from the implant container

1. Position the screwdriver directly in line with the screw.

2. Push the tension sleeve down until it clicks.

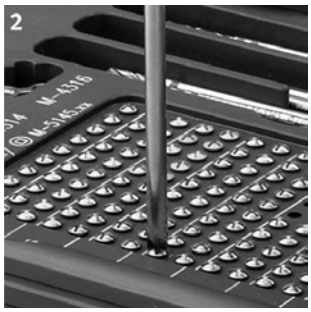


3. The screw is held securely by the tension sleeve.

Screwdriver with self-holding blade: Removal of screws from the implant container

1. Position the screwdriver directly in line with the screw.

2. Pick up the screw by applying slight axial pressure downwards before retracting the screwdriver with the attached screw from the implant container.



3. The screw is held securely by the blade.

Notice: The screw will not hold without this axial pressure. Ensure that screw and screwdriver stay in line during extraction (no tilting).

Appendix
Implants and Instruments

For detailed ordering information please refer to the MODUS Ordering Catalogue, also available at www.medartis.com.

Plates

Art. No.	Art. No.	Art. No.
M-4100	M-4174	M-4272
M-4102	M-4180	M-4273
M-4104	M-4182	M-4274
M-4106	M-4184	M-4275
M-4108	M-4186	M-4276
M-4110	M-4188	M-4277
M-4112	M-4190	M-4278
M-4114	M-4192	M-4279
M-4116	M-4194	M-4280
M-4120	M-4196	M-4281
M-4122	M-4200	M-4282
M-4124	M-4202	M-4288
M-4126	M-4204	M-4290
M-4128	M-4214	M-4348
M-4130	M-4216	M-4350
M-4132	M-4220	M-4400
M-4134	M-4222	M-4402
M-4136	M-4224	M-4404
M-4138	M-4226	M-4406
M-4140	M-4228	M-4408
M-4142	M-4242	M-4410
M-4144	M-4244	M-4412
M-4146	M-4246	M-4414
M-4148	M-4248	M-4416
M-4150	M-4250	M-4418
M-4152	M-4252	M-4420
M-4156	M-4254	M-4422
M-4158	M-4256	M-4424
M-4166	M-4258	M-4426
M-4168	M-4262	
M-4170	M-4264	
M-4172	M-4271	

Screws

Art. No.	Art. No.	Art. No.
M-5100.02	M-5121.06	M-5223.05
M-5100.02/1	M-5121.06/1	M-5223.05/1
M-5100.03	M-5123.04	M-5223.06
M-5100.03/1	M-5123.04/1	M-5223.06/1
M-5100.04	M-5123.05	M-5230.05
M-5100.04/1	M-5123.05/1	M-5230.05/1
M-5100.05	M-5123.06	M-5240.04
M-5100.05/1	M-5123.06/1	M-5240.04/1
M-5100.06	M-5130.05	M-5240.05
M-5100.06/1	M-5130.05/1	M-5240.05/1
M-5110.02	M-5140.04	M-5240.06
M-5110.02/1	M-5140.04/1	M-5240.06/1
M-5110.03	M-5140.05	M-5243.05
M-5110.03/1	M-5140.05/1	M-5243.05/1
M-5110.04	M-5140.06	M-5243.06
M-5110.04/1	M-5140.06/1	M-5243.06/1
M-5110.05	M-5143.05	M-5250.05
M-5110.05/1	M-5143.05/1	M-5250.05/1
M-5110.06	M-5143.06	
M-5110.06/1	M-5143.06/1	
M-5120.03	M-5150.05	
M-5120.03/1	M-5150.05/1	
M-5120.04	M-5220.03	
M-5120.04/1	M-5220.03/1	
M-5120.05	M-5220.04	
M-5120.05/1	M-5220.04/1	
M-5120.06	M-5220.05	
M-5120.06/1	M-5220.05/1	
M-5121.04	M-5220.06	
M-5121.04/1	M-5220.06/1	
M-5121.05	M-5223.04	
M-5121.05/1	M-5223.04/1	

Instruments

Art. No.	Art. No.
M-2100	M-2540
M-2101	M-2543
M-2102	M-2551
M-2103	M-2552
M-2104	M-2553
M-2110	M-2598
M-2112	M-2662
M-2140	M-2663
M-2141	M-3180
M-2142	
M-2150	
M-2160	
M-2170	
M-2171	
M-2172	
M-2173	
M-2191	
M-2192	
M-2193	
M-2420	
M-2501	
M-2502	
M-2503	
M-2510	
M-2511	
M-2512	
M-2513	
M-2520	
M-2521	
M-2522	
M-2523	
M-2530	

Twist Drills

Art. No.
M-3112
M-3113
M-3121
M-3162
M-3163
M-3172
M-3173
M-3183
M-3192
M-3212
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Publications

1. Heidemann, W.; Terheyden, H.; Gerlach, K. L.
Analysis of the osseous / metal interface of drill free screws and self-tapping screws
Journal of Cranio-Maxillofacial Surgery (2001) 29, 69–74

2. Heidemann, W.; Terheyden, H.; Gerlach, K. L.
In-vivo-Untersuchungen zum Schrauben-Knochen-Kontakt von Drill-Free-Schrauben und herkömmlichen selbstschneidenden Schrauben
Mund Kiefer GesichtsChir 5 2001: 17–21

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