





Cervical Plate System

System

The HERO® anterior cervical plate system serves to stabilise the cervical spine. It is intended for use with angle-variable single or standard screws or expandable bone screws (expansion screws), as well as a combination of all screw types (hybrid) in the cervical spine from C2 to C7.

Expansion screws offer additional stability for monocortical anchoring even if the bone substance is poor. HERO® 3 and 4-segment plates have multiposition bores, which provide the surgeon with additional length variation options for multi-segmental restorations.

HERO® provides the following product-specific advantages:

Anatomical

- Expandable bone screws
- Angle-variable bone screws
- Pre-formed plates
- · Slim, concave plate design
- Flush closure of upper edge of plate and screw

Transparent

- · Drilling gauges with multiple borehole options
- Colour-coded screws
- Self-tapping screws
- "Pick and Place" handling of the screws

Stable

- · Secure anterior support structure
- Fixed screw anchoring in the plate
- Large instrument receptacles

Flexible

- · Mono-segmental plates
- Poly-segmental plates
- Extra long screws (up to 22 mm)
- · Large selection of screws
- Large selection of plates
- Multi-positional bores in poly-segmental plates
- Angular variability up to 30° from caudal to cranial

Universal

- Expandable bone screws for weakened bone substance
- Expandable bone screws for revision surgery
- Unique plate/screw locking mechanism





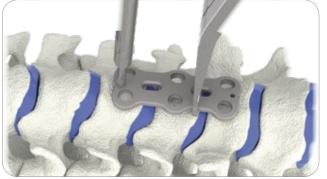


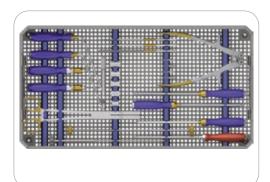




HERO®

Cervical Plate System







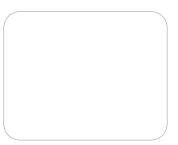








- Anatomical
- Transparent
- Universal
- Flexible
- Stable









HERO® material

All the components are made from titanium alloy Ti6Al4V according to DIN EN ISO 5832-3.

HERO® screws

The external thread of the screws is designed as self-tapping bone threads. The multiple-slotted flat-side of the screw head serves as instrument receptacle. All HERO® screws can be inserted at variable angles (cranial-caudal $\pm 15^{\circ}$ and medial-lateral $\pm 6^{\circ}$). The drill must be used with the Drill Guide for optimum functioning of the screws and for centring the bone screw passage.

HERO® Standard Screws (Fig. 1)

The locking screw with the identical external thread can be screwed into the internal thread, which triggers the locking mechanism and fixes the screw head in the plate bore. Only Standard Screws may be used for bicortical screw fixation.

HERO® Expansion Screws (Fig. 2)

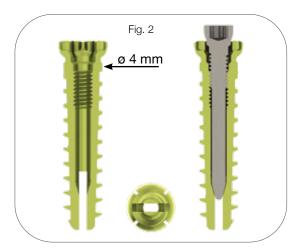
The locking screw with the identical external thread can be screwed into the internal thread, which triggers the locking mechanism and fixes the screw head in the plate bore. For Expansion Screws, the slotted screw shaft spreads at the same time and guarantees a secure fit in the case of poor bone quality or revision surgery. Since the locking screws of the Expansion Screws have different lengths, it is necessary to assign the correct locking screw to the corresponding bone screw.

HERO® Single Screws (Fig. 3)

Single Screws do not require an additional locking screw. They are locked in place in the plate via the specially-designed geometry of the screw head.

Screws







Indications

The HERO® cervical plate system is designed for the surgical treatment of diseases and injuries of the cervical spine from C2 to C7 in patients in whom general skeletal growth has ceased, in particular for indications such as:

- Degenerative discopathy
- Fractures
- Tumours
- Pseudarthrosis
- · Spinal canal stenosis
- · Cervical myelopathy
- Deformities (i.e. kyphosis, lordosis and/or scoliosis)
- Revisions

Contraindications

Contraindications may be either relative or absolute. The selection of a particular implant must be weighed carefully against the overall assessment of the patient. The following conditions can have an adverse impact on the chances of successful surgery:

- All destructive and inflammatory diseases of the cervical vertebrae and of the motion segments such as tumors, spondylitis and fractures with a high degree of instability, with pronounced static and structural alteration of the spine and the segment structure, which require a vertebral body replacement and other measures to reconstruct and stabilize the segment.
- · acute infections or significant risks of infection (weakened immune system)
- · signs of local inflammations
- · fever or leukocytosis
- morbid obesity
- pregnancy
- physical diseases
- · severe anatomical deformities caused by congenital abnormalities
- Any other medical or surgical condition, which prevents a possible improvement by the
 use of the implant, such as the presence of congenital abnormalities, a fracture close
 to the operation site, increase of the deposition rate which is not explained by other
 disease patterns, elevated white blood cell count (WBC) or a pronounced leftward shift
 in the differential WBC.
- Articular diseases, bone resorption, osteopenia, osteomalacia and/or osteoporosis are relative contraindications as these may limit the degree of achievable correction or stabilization.
- Any neuromuscular disease that would place excess strain on the implant during the healing period.
- known hereditary or acquired bone brittleness or calcification problems
- Suspicion of a metal allergy or intolerance, and documented metal allergy or intolerance.
 Appropriate tests should be carried out
- · all cases in which the use of components made of various metals or alloys is required
- · all cases in which no fusion is required
- all cases in which the implant components selected for use are too big or too small to achieve a satisfactory result
- any patient with inadequate tissue structure at the surgical site or with inadequate bone stock or bone quality
- Any patient in whom the use of implant is hindered by anatomical structures or where these structures would restrict the physiological performance.
- · any patient who is unwilling to follow postoperative instructions
- · all cases not described under the indications

HERO® screw/plate interlocking mechanism

The variable-angle screws guarantee movement of up to 30° from caudal to cranial while maintaining the sagittal alignment of the screws. This flexibility allows easier screw placement without compromising the stability of the construct.

HERO® plates have a thickness of 2 mm, a width of 17.3 mm, are lordotically pre-bent and have a curve of 12.8 mm in either a mono or bisegmental design.

In addition to the corner holes, polysegmental plates also have variable slot holes (Fig. 4) and are thus reinforced in the middle to 18.8 mm. These multi-position drill holes consist of 3 individual drill holes, each 3 mm apart, in order to offer the surgeon further length variation options for multisegmental procedures.

A total of 23 variations are available (from 21 mm to 97 mm).

The plate holes have the same spherical geometry as the screw heads (Fig. 5). The centre of the sphere is located in the upper part of the plate. This means that the bore diameter on the upper side of the plate is larger than on the lower side, which prevents the screw from "penetrating" through the plate.

If the spherical head of the bone screw meets the upper edge of the plate hole (Fig 6 and 7) when screwing in, the screw head pivots inwards, and the screw can be screwed into the plate holes.

The locking screw is screwed in with the Locking Screw Inserter. This restricts the screw head from tapering inwards.

Plates

The flat-sided instrument receptacles for all screws, as well as the hexagon socket of the locking screws (in the Standard and Expansion Screws), are extremely large and therefore robust and durable.

HERO®

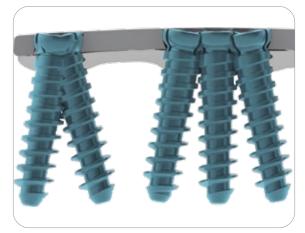


Fig. 4



Fig. 5



Fig. 6

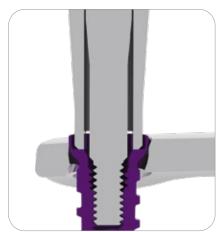
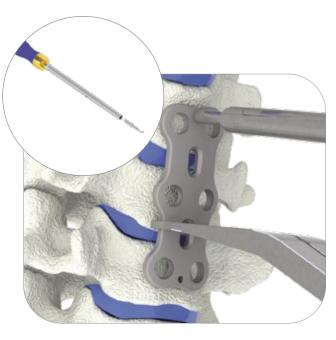


Fig. 7







Adjusting the plate (optional)

Although the plates are already anatomically pre-bent, with the help of the Plate Bender they can also be lordotically or kyphotically adapted to the specific conditions of the patient.

Note:

Bending in the area of the screw holes causes the screw seat to deteriorate and reduces biomechanical stability. Therefore, the plate must be bent between the screw holes. Generally, the plate may only be bent in one direction.

Positioning the plate

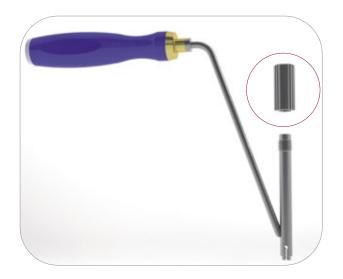
The plates can be held with the Plate Holder or Plate Positioner and positioned on the vertebrae. The central slotted hole windows on the plates contain two threads into which the Plate Positioner can be screwed.

Temporary fixation with Fixation Pins

The Fixation Pins are inserted into the Pin Driver until it locks into place in the locking spring located on the Pin Driver. Care should be taken to align the hexagonal profile so that the Distraction Pin is correctly positioned in the Pin Driver. The Fixation Pins are inserted into the Pin Driver and screwed into the vertebrae at the cranial and/or caudal ends of the plate.

Note:

The Fixation Pins should be screwed in as far as possible. It is important to make sure that these are inserted in a straight position, in order to avoid breaking the Fixation Pins and to be able to remove them afterwards without any problems.







Preparation of the depth stops for the Drill Guide

Different depth stops are available for the various screw lengths to prevent the drill or tap from being screwed in too deeply. The depth stop is screwed onto the Drill Guide according to the desired screw length.

Caution:

The Drill Guide must not be used without a depth stop.

Preparation of the screw channel

The straight handle can be used both with the drill and the tap. First, click the Drill Guide into the drill hole of the plate. Insert the drill into the Drill Guide and turn it clockwise to prepare the screw channel. The drill must be screwed in as far as it will go.

Note:

When revising an external system, the screw holes must be prepared again using the ${\sf HERO}^\circledR$ plates and the Drill Guide due to possible differences in the hole spacing and/or screw diameters.

Drilling manoeuvres and thread cutting must always be carried out with the aid of the Drill Guide and under image converter monitoring.

Preparation of the screw channel with hard bone

If the bone structure is hard, first drill with the drill (Drill 2.5 mm), then with the supplied drill for hard bone (Drill HB) and then precut the thread with the tap (Tap \emptyset 4).

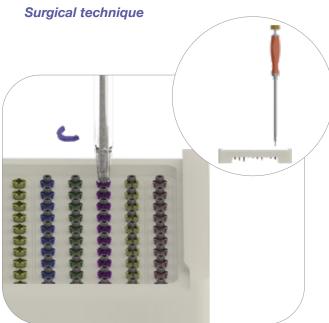
Caution:

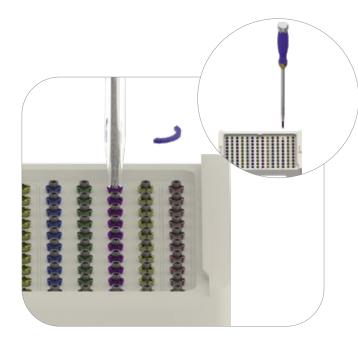
For hard bone structure, either Standard Screws or Single Screws may be used. The Expansion Screws may not be used with hard bone structure.

Note:

The drill for hard bone (Drill HB) may only be used with hard bone structure. Drilling manoeuvres and thread cutting must always be carried out with the aid of the Drill Guide and under image converter monitoring.







Single Screws

The Single Screws have a self-drilling thread and no locking screws. The Drill must be used with the Drill Guide for optimum functioning of the screws and for centring the screw passage. The Single Screws are implanted using the Single Screwdriver, which attaches completely to the screw. To reach this position, the Single Screwdriver must be pressed downwards slightly when it is placed on the screw. The screw heads and plate holes have been aligned in such a way that the screw head itself locks into the plate.

For Standard and Expansion Screws, an additional safety mechanism is triggered by the locking screw to minimise the risk of a screw back-out.

Standard and Expansion Screws

To remove the locking screw of the bone screw to be implanted, insert the Locking Screw Driver into the Locking Screw Inserter 4P. Then insert the Locking Screw Inserter into the instrument receptacles of the bone screw and insert the 4P Locking Screw Driver into the hexalobular internal of the Locking Screw. Remove the locking screw from the bone screw by turning the Locking Screw Driver anti-clockwise and lock it temporarily in the Locking Screw Inserter 4P.

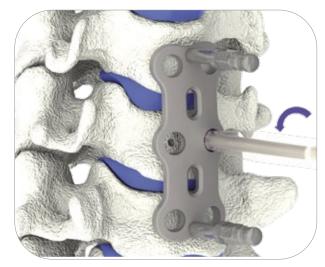
Preparing the screws

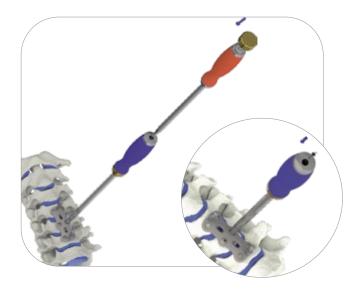
To do this, insert the Screw Inserter Shaft into the Hero Screw Driver. Insert the Hero Screw Driver into the instrument receptacles of the bone screw then screw in the Screw Inserter Shaft and tighten it hand-tight. This ensures a stable connection between the bone screw and the Hero Screw Driver.

Note

The Screw Inserter Shaft must be tightened completely to ensure a firm connection between the screw and the instrument. The Hero Screw Driver can be mounted more easily if the Screw Inserter Shaft is screwed into the screw first. In this way, Standard and Expansion Screws can be extracted from the screw box and implanted easily.







Inserting the bone screws

For bisegmental instrumentation, it is recommended to insert the bone screws in the middle level first. When using 3 or 4-segment plates, you can choose between 3 hole positions for screwing in the screws. Variable-angle screw insertion is also possible here at any time. Screw in Standard or Expansion Screws with the Hero Screw Driver until they snap noticeably into the plate and are firmly seated.

The Single Screws are inserted using the Single Screw Driver until they snap noticeably into the plate and are firmly seated.

Caution

During the implantation of the screw, it must be ensured that the connection between the Screw Inserter Shaft, Hero Screw Driver and implant is firm and that there is no axial pressure on the Screw Inserter Shaft (1). This means that the Hero Screw Driver (2) and the Screw Inserter Shaft can rotate evenly and that the firm connection between the implant and the instrument is ensured.

Loosening of the Screw Inserter Shaft

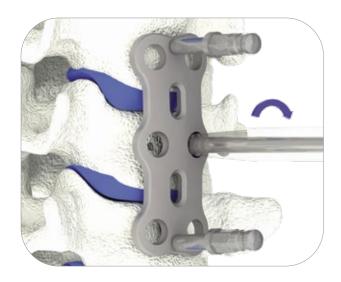
After the bone screw has been implanted, the Screw Inserter Shaft must be loosened from the screw by turning it anti-clockwise and then removed from the Hero Screw Driver. The Hero Screw Driver should not yet be removed, as it acts as a rotational brake arm when inserting the locking screw.

Fitting the locking screws

The locking screw that was previously removed from the bone screw (Standard or Expansion Screw) is inserted with the Locking Screw Inserter 4P or manually through the Hero Screw Driver opening.

Caution:

When using Expansion Screws, care must be taken to ensure the correct assignment of the locking screws as these have different lengths.



Fixing the locking screws

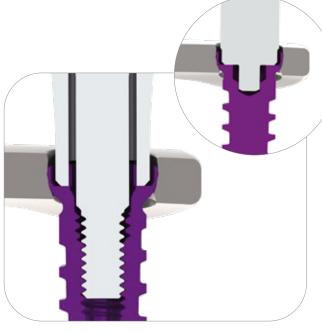
With the Locking Screw Driver, which should be guided through the Hero Screw Driver, screw in the locking screw until it stops; this will trigger an additional safety mechanism for the Standard Screws and Expansion Screws. When using Expansion Screws, the screw shaft is splayed simultaneously and provides a secure anchoring if there is poor bone quality and/or in cases of revisions.



Final construction

Finally, the Pin Driver is pushed onto the respective Fixation Pin until it stops. Care should be taken to align the hexagonal profile. The Fixation Pins are then screwed on anti-clockwise. The locking spring located on the Pin Driver ensures that the Fixation Pin is not lost.

Final check on the structure with X-ray control images taken in two planes. Cleanse the surgical area and close the wound.



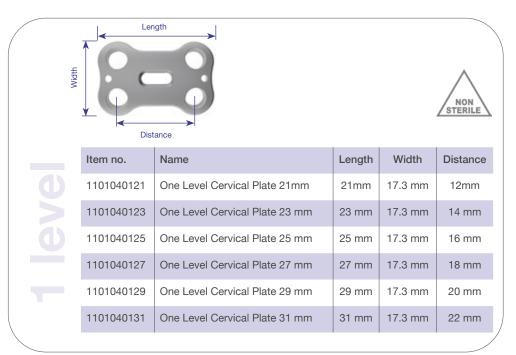
Screw removal

If it becomes necessary to remove the screws, the Standard and Expansion Screws should first be loosened and then the locking screw should be loosened before removing the bone screws. The Standard or Expansion Screws can subsequently be removed by turning the Hero Screw Driver anti-clockwise. For deeply embedded screws, it is recommended to first loosen the implant using the Single Screwdriver and then to remove it in the above-mentioned way. The Single Screws can be removed using the Single Screw Driver.

Instruments

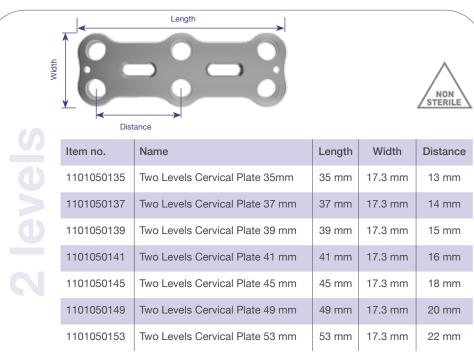
Item no.	Name		Item no.	Name	
1101010000	Screwdriver		1501010011	Pin Driver	
1101010001	Locking Screwdriver	<u></u>	1101010010	Fixation Pin	
1101010002	Tap 4 mm		1101010011	Standard AO Handle	
1101010003	Drill 2.5 mm		1101010012	Plate Positioner	
1101010007	Drill HB (drill for hard bones)	Drill HB			
1101010004	Drill Guide		1101010013	Single Screwdriver	
1101010005	Plate Holder		1101010014	Screw Inserter Shaft	
1101010006	Plate Bender		1101010016	Locking Screw Inserter 4P	

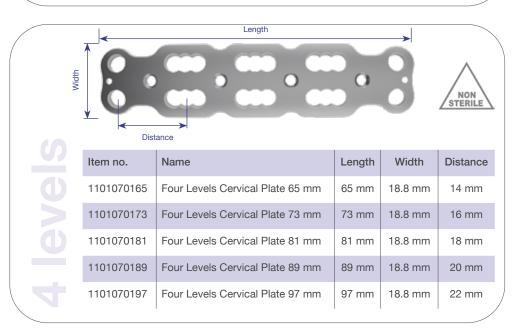
Implants



NON Distance Item no. Name Length Width Distance 1101060151 Three Levels Cervical Plate 51 mm 51 mm 18.8 mm 14 mm 1101060157 Three Levels Cervical Plate 57 mm 57 mm 18.8 mm 16 mm 1101060163 Three Levels Cervical Plate 63 mm 63 mm 18.8 mm 18 mm 1101060169 Three Levels Cervical Plate 69 mm 69 mm 18.8 mm 20 mm 1101060175 Three Levels Cervical Plate 75 mm 75 mm 18.8 mm 22 mm

CERVICAL PLATES non-sterile





CERVICAL PLATES sterile

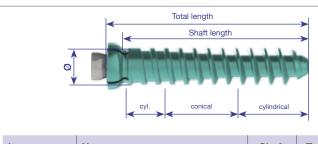


		Length			
	Width			[STERILE
(0)		Distance			
	Item no.	Name	Length	Width	Distance
	1101050135-S	Two Levels Cervical Plate 35 mm sterile	35 mm	1) (3 n/m	13 mm
	1101050137-S	Two Levels Cervical Plate 37 mm sterile	_3 ⁻ (mn)	17.3 mm	14 mm
	1101050139-S	Two Levels Cervical Plate 39 mm sterile	39 mm	17.3 mm	15 mm
	1101050141-S	Two Levels Cervical Plate 41 Jum sterile	41 mm	17.3 mm	16 mm
	1101050145-S	Two Levels Corvica Frate 45 mm sterile	45 mm	17.3 mm	18 mm
	1101050149-5	Two evels Cervical Plate 49 mm sterile	49 mm	17.3 mm	20 mm
	1101050153-S	wo Levels Cervical Plate 53 mm sterile	53 mm	17.3 mm	22 mm



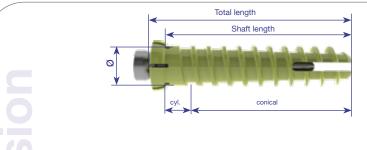


SCREWS non-sterile



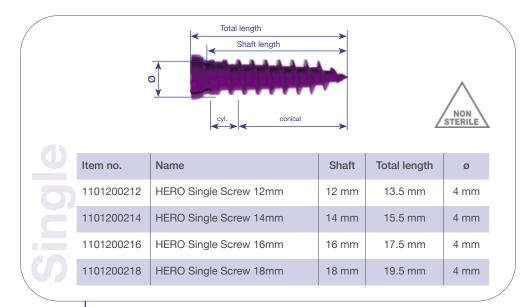


Item no.	Name	Shaft	Total length	Ø
1101210212	HERO Standard Screw 4P 12 mm	12 mm	13.5 mm	4 mm
1101210214	HERO Standard Screw 4P 14 mm	14 mm	15.5 mm	4 mm
1101210216	HERO Standard Screw 4P 16 mm	16 mm	17.5 mm	4 mm
1101210218	HERO Standard Screw 4P 18 mm	18 mm	19.5 mm	4 mm
1101210220	HERO Standard Screw 4P 20 mm	20 mm	21.5 mm	4 mm
1101210222	HERO Standard Screw 4P 22 mm	22 mm	23.5 mm	4 mm





Item no.	Name	Shaft	Total length	Ø
1101220212	HERO Expansion Screw 4P 12 mm	12 mm	13.5 mm	4 mm
1101220214	HERO Expansion Screw 4P 14 mm	14 mm	15.5 mm	4 mm
1101220216	HERO Expansion Screw 4P 16 mm	16 mm	17.5 mm	4 mm
1101220218	HERO Expansion Screw 4P 18 mm	18 mm	19.5 mm	4 mm





SCREWS sterile









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