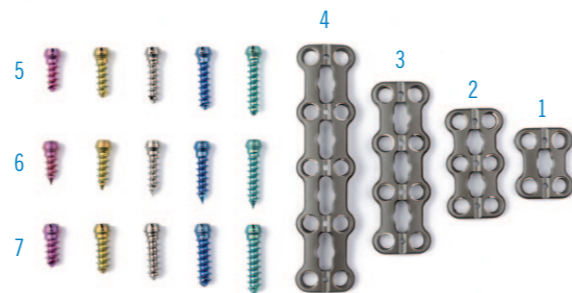


ACP

Anterior Cervical Plate

Implants		
1-level plate - max interaxis 12 - 30mm	ACP-01T5XX	1
2-level plate - max interaxis 26 - 48mm	ACP-02T5XX	2
3-level plate - max interaxis 45 - 72mm	ACP-03T5XX	3
4-level plate - max interaxis 60 - 104mm	ACP-04T5XX	4
5-level plate - max interaxis 95 - 120mm	ACP-05T5XX*	
Self-tapping screw Ø 4mm - length 10mm	ACP-10T510	5
Self-tapping screw Ø 4mm - length 12mm	ACP-10T512	5
Self-tapping screw Ø 4mm - length 14mm	ACP-10T514	5
Self-tapping screw Ø 4mm - length 16mm	ACP-10T516	5
Self-tapping screw Ø 4mm - length 18mm	ACP-10T518	5
Self-drilling screw Ø 4mm - length 10mm	ACP-20T510	6
Self-drilling screw Ø 4mm - length 12mm	ACP-20T512	6
Self-drilling screw Ø 4mm - length 14mm	ACP-20T514	6
Self-drilling screw Ø 4mm - length 16mm	ACP-20T516	6
Self-drilling screw Ø 4mm - length 18mm	ACP-20T518	6
Self-tapping screw Ø 4,5mm - length 10mm	ACP-11T510	7
Self-tapping screw Ø 4,5mm - length 12mm	ACP-11T512	7
Self-tapping screw Ø 4,5mm - length 14mm	ACP-11T514	7
Self-tapping screw Ø 4,5mm - length 16mm	ACP-11T516	7
Self-tapping screw Ø 4,5mm - length 18mm	ACP-11T518	7

Instruments	
Complete instrument set	ACP-0001S



*Available on request

INDICATIONS

Appropriately used, Sinteplastek ACP anterior cervical plate is indicated to promote the development of a solid vertebral arthrodesis of the cervical spine, by means of an anterior approach. It can be used in case of cervical instability due to different traumatic and degenerative pathologies, neoplasia, stenosis or pseudoarthrosis.

CONTRAINDICATIONS

The contraindications to the implant of Sinteplastek ACP anterior cervical plate are analogous to those of similar products currently available on the market and include but are not limited to the following:

ABSOLUTE

- Active systemic infections localised in the implant area
- Allergy to the materials used
- Uncooperative patients who are unable to follow the prescriptions (mental illness, drug abuse, alcoholism as a possible cause of failure to follow a proper post-operative period, physiotherapy or other physical therapy)

RELATIVE:

- Severe muscle, neurological or vascular diseases
- Fever or leukocytosis
- Pregnancy, except for the treatment of unstable vertebral fractures
- Any condition that might significantly affect the fusion and related contraindications (e.g., cancer, diabetes, osteomalacia, heavy smoking, obesity).
- Previous attempts of fusion of the levels to be treated
- Signs of phlogosis of the implant area
- Severe osteoporosis
- Any condition that may not have been described in the indications for use

If Sinteplastek ACP anterior cervical plate is considered the best solution for the patient, and if the latter presents one or more of the above contraindications, it is absolutely necessary to inform him/her about any possible adverse effect that may influence the success of the procedure.

Sinteplastek S.r.l.

Commercial, administrative and registered office:

Via E. Fermi 44 – 20090 Assago (MI) – Italia
 Tel. +39 02 45 79 02 31 – Fax +39 02 45 79 02 66
 E-mail: sinteplastek@alapec.it
 VAT NO. 04874470968 - Fully paid up capital € 100.000,00
 National Business Register: Milan (Italy) no. 1778805

Manufacturing Plant:

Via Aquileia 33/H – 20021 Baranzate (MI) – Italia
 Tel. +39 02 45 79 02 31
 Fax +39 02 45 79 02 66
 E-mail: sinteplastek@alapec.it

Sinteplastek LLC

407 Lincoln Rd. Suite 10/L
 33139 Miami Beach (FL) – USA
 Tel. +1 305 67 36 226
 Fax +1 305 67 33 312
 E-mail: sinteplastek@alapec.it



ACP

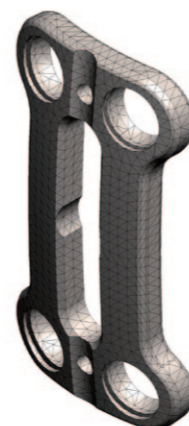
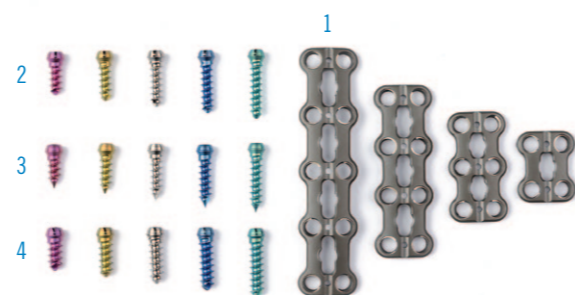
Anterior Cervical Plate



ACP

Anterior Cervical Plate

TECHNOLOGY AND INNOVATION



Sintea Plustek ACP anterior cervical plate is indicated to promote the development of a solid vertebral arthrodesis of the cervical spine by means of an anterior approach.

It was designed to ensure a good anatomical adaptability. The system is characterized by a screw anti-migration system. The screws, which are polyaxial and are available in a self-tapping and self-drilling version, are supplied with standard and recovery diameter in five different lengths (10mm – 12mm – 14mm – 16mm – 18mm).

The plates are available in different sizes, allowing the stabilization of vertebral bodies from 1 to 5 levels, and with different interaxis lengths between the holes. Moreover, they are characterized by a 28mm medio-lateral radius of curvature and a 2.5mm thickness. The holes for screw insertion in the upper part of the plate are 10° cranio-caudally angled.

The plate has a long and thin central opening that can be used to control its correct positioning with respect to the vertebral bodies.

In order to guarantee optimal biomechanical performances and to facilitate the use of diagnostic imaging the implants are made of biocompatible titanium alloy.

All components of the system are compliant with Directive 93/42/EEC.

COMPONENTS

1. PLATE
2. SELF-TAPPING SCREWS \varnothing 4mm
3. SELF-DRILLING SCREWS \varnothing 4mm
4. SELF-TAPPING SCREWS \varnothing 4.5mm

DESIGN AND ENGINEERING

All elements of the ACP system were designed using the standard methods of continuum mechanics stress analysis.

The results were validated both according to the Finite Elements Method, in order to establish optimal dimensioning in relation to the device requirements and user specification, as well as by static and fatigue experimental tests, so as to reproduce the most critical loading conditions.

INNOVATIVE ASPECTS

The plates are characterized by an anti-migration system made of an elastic element suitably placed inside the plate. During the screw insertion, this elastic element is deformed and it becomes loose, due to the peculiar shape of the screw head, until it reaches the maximum diameter and it passes over the largest part of the screw head. After this point, the element returns to its un-deformed shape. With this configuration the risk of a pull-out is extremely reduced and the screw can only be removed by use of the appropriate screwdriver.

MAIN FEATURES

- EFFICIENT ANTI-MIGRATION SYSTEM
- POLYAXIAL SCREWS
- WIDE RANGE OF SIZES: FROM 1 TO 5 LEVELS IN DIFFERENT INTERAXIS
- THIN PLATE
- LATERO-MEDIAL 28MM CURVATURE
- CENTRAL OPENING TO CHECK CORRECT POSITIONING OF THE PLATE
- SELF-TAPPING, SELF-DRILLING AND RECOVERY SCREWS