SPIDER SCREW ®

CE 0476

Temporary orthodontic anchorage system

I+DC
ealth Development Company

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SPIDER SCREW ®

0476

Temporary orthodontic anchorage system

Nothing has been left to chance.

The Spider Screw has obtained an international patent since its inception, due to its innovative characteristics: the simultaneous presence of external and internal rectangular slots and round internal slots.

The SPIDER SCREW'S geometry is a result of careful design in each of its three components: the ORTHODONTIC HEAD, the TRANSMUCOSAL PORTION and the INFRABONY PORTION.

The SPIDER SCREW has been developed to offer a number of versatile anchorage options capable of immediate loading. Immediate loading is possible because the SPIDER SCREW is a non osteointegratable implant and consequently force can be applied immediately after placement. The applied force can range from 50 to 300 grams depending on screw choice, bone quality, and the desired orthodontic movement.
The SPIDER SCREW's design is extremely versatile, due to its small dimensions and unique design. It is easily placed in either the maxilla or mandible, even where access is limited and bone quality is less than ideal. Placement is simplified by the self-drilling feature found in the K1 and K2 systems.

The SPIDER SCREW is an anchorage device that can be used during every phase of orthodontic treatment and is suitable for symmetric or asymmetric anchorage. The screws assists in the success of orthodontic treatment, both in adults and adolescents, by reducing treatment time without patient co-operation.

The SPIDER SCREWS are provided in different diameters and lengths so to be placed in different sites (edentulous ridges, palate, tuberosity, interadicular areas, infrazygomatic crest, retromolar region, mandibular ramus and synfisis).

The SPIDER SCREW is made in Grade 5 Titanium alloy, supplied clean and sterile inside a sealed polypropylene bottle. The screws have been cleaned, decontaminated and sterilized via gamma radiation. Included in the package are three removable stickers containing important information (device name, reference code, lot number, etc.) which can be applied to the patient's record card for traceability.

1.

2.

3.

4.

5.

ORTHODONTIC HEAD (fig. 1,2)

The orthodontic head was designed to facilitate appliance (wires, springs, etc.) placement. There is a bracket like head featuring two intersecting .022" slots. The under tie wing area can also function as another .022" x .025" slot and features two intersecting slots of .027" in diameter with chamfered inlets to simplify insertion of wires or ligatures. The head is available different dimensions: the largers (Spider Screw K2 Regular Plus 2 mm, Spider Screw K2 1,9 mm and Spider Screw Konic 2/2,3 mm) are for palatal use; the smallers (Spider Screw K1 1,5 mm, Spider Screw C1 1,5 mm, and Spider Pin 1,3 mm) are for patient comfort.

TRANSMUCOSAL PORTION (fig. 3,4)

The length of the transmucosal portion is variable and allows for optimal adaptation to different intraoral mucosa thicknesses during bio-maintenance. Short for areas of thin attached gingiva. Long for areas with thick or freely moveable tissues. The transmucosal portion is polished with a special treatment to help avoid soft tissue irritation and make cleaning easier to accomplish.

INTRABONY PORTION (fig. 5)

The Spider Screw's thread shape has an asymmetrical profile making it easy to place while ensuring maximum stability and avoiding bone stress. Spider Screw K1 1,5 mm, Spider Screw K2 1,9 mm and Spider Screw Self-Ligating, tapered thread, are self-drilling and self-tapping which makes pre-drilling before insertion unnecessary - dependant upon bone structure. This makes the Spider Screw K1, K2 and Self-Ligating easy to place while reducing the risk of root damage. Spider Screw C1 1,5 mm and Spider PIN 1,3 mm cylindrical thread, require pre-drilling and are used in areas that have poor bone quality or greater retention requirements.

Insertion Sites:

MAXILLA

Infrazygomatic crest

Edentulous ridges

Palate

Tuberosity

Interadicular areas

MANDIBULA

Edentulous ridges

Retromolar region

Mandibular ramus

Interadicular areas

Synfisis

INDICATIONS

SPIDER SCREW ANCHORAGE SYSTEM (SSAS) allows sagittal and vertical movement of all teeth (intrusion, extrusion, distalization and mesialization) and can be used for treating the following:

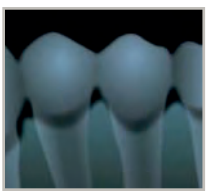
> Class I, Class II, Class III malocclusion treatment;
> Anchorage Recovery;
> Anchorage Reinforcement;
> Asymmetrical case management;
> Uprighting of upper and lower molars;
> Correction of over erupted teeth (molar, premolar, incisors);
> Deep bite and open bite conditions;
> Pre-Prosthetic Orthodontic treatment;
> Borderline cases;
> Orthodontic treatment without patient cooperation (MBGM system).

GENERAL INFORMATION

The placement of SPIDER SCREW is a procedure requiring specific knowledge of anatomy and technique. It is absolutely necessary that it is carried out by specifically trained doctors. It is important to know that improper patient selection and/or incorrect technique can cause placement failure and/or loss of supporting bone.
An effective and complete screening of the patient must be performed and each case carefully evaluated. A very thorough examination is needed, as well as anatomical reference for the evaluation of bone quantity and quality using radiographic research (Long Cone Endoral Radiograph, Orthopantograph, Teleradiography, and Computerized Tomography).

Carefully read the instructions for use inside the package before the Spider Screw placement. The SPIDER SCREW is for single use only and should not be reused. Use only the instruments mentioned in this catalog, making sure that all the instruments are sterilized and efficient.

It is suggested to disinfect the insertion area and give local anesthesia as needed. It is very important that the clinician attends a training course for a complete overview of all the possible applications, as this catalog shows only a few.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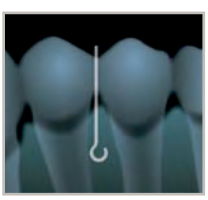
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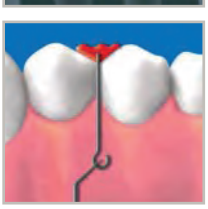
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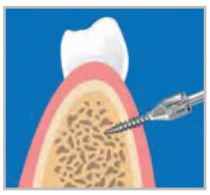
TAPERED THREAD AND SELF-LIGATING SCREW

If a SPIDER SCREW is to be inserted in an edentulous area where there is bone availability, references from a panoramic radiograph can be sufficient.

1. In areas close to delicate anatomical structures, such as interadicular spaces, a long cone radiograph is recommended.
2. A surgical splint can be made with orthodontic wire, fixing it to the teeth with acrylic or thermoplastic resin. The orthodontic wire is inserted in the acrylic resin and is appropriately bent so that its tip corresponds to the point of insertion of the SPIDER SCREW.
3. Use a periapical radiograph (by using the long-cone parallel technique) to verify the correct placement of the orthodontic wire.
4. The insertion site can be marked with a pressure point or methylene blue dot on the soft tissue. In mobile mucosa it is recommended to leave the surgical guide in place during the drilling phase and/or the screw insertion.



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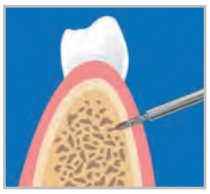

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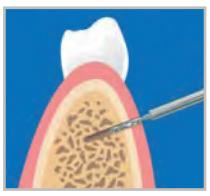
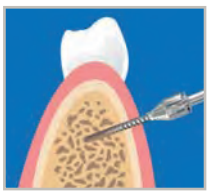


5.a



6.a

5. After site disinfection (chlorhexidine) insert the SPIDER K1 or K2 using the pick-up driver shaft DSP-5052S (insert the Spider K1 or K2 SELF-LIGATING using the pick-up driver shaft DSP-5652S). It is also possible to use the contra-angle pick-up driver at low speed 25/30 rpm (DPQ-2820 for the Spider Screw K1 or K2 Tapered Thread, DPQ-3420 for the Spider Screw Self-Ligating).
   In order to avoid excessive torque stress during insertion, which could cause bone compression and consequent recession or cause the screw to break, it is recommended to use a technique of alternating between screwing and unscrewing to gradually ease the screw into position. Final placement is achieved by using the handle driver DSQ-2824 for the Spider Screw K1 or K2 Tapered Thread or DSQ-3424 for the Spider Screw Self-Ligating, to complete the insertion as this provides the most controlled tactile method.
6. In the case of very compact bone use a spiral drill (FSC-1108 for K1 Tapered Thread and Self-ligating or FSC-1309 for K2 Tapered Thread and Self-ligating) to make a pilot hole which makes screw insertion easy to perform.

SPIDER SCREW C1 AND PIN PLACEMENT

Follow points 1 to 4 as above.

5a. After site disinfection (chlorhexidine) the spiral drill is used to perforate the soft tissue and cortical bone (no incision needed). Cold irrigation is used during the drilling procedure (5°C/41°F). Use the Ø 0,9 mm drill for the SPIDER SCREW PIN and the Ø 1,2 mm drill for the C1.

6a. You can choose between two options: manual or mechanical insertion. For manual insertion use DSP-2352S for the Spider Screw PIN Ø 1,3 mm and DSP-5052S for the Spider Screw C1 Ø 1,5 mm. For mechanical insertion use the contra angle pick-up driver DPQ-2352S for the Spider Screw PIN Ø 1,3 mm and DPQ-2820 for the Spider Screw C1 Ø 1,5 mm mounted on a low speed contra-angle handpiece (25/30 rpm). Final placement is achieved by using the handle driver to complete the insertion as this provides the most controlled tactile method.

POST APPLICATION PATIENT INSTRUCTION

Application of chlorhexidine rinse 2 – 3 times per day for the first 7 days.
Perform normal hygiene procedures. The patient should brush the screw normally as a tooth.

SPIDER SCREW REMOVAL

To remove the SPIDER SCREW, it is simply unscrewed with the appropriate screwdriver. For anterior and lateral areas is advisable to use the handle driver. While for posterior areas is advisable to unscrew with contra angle pick-up driver. This can be accomplished with or without anesthesia.

If the Spider Screw does not unscrew easily it is recommended to use a technique of alternating between unscrewing and screwing. Healing takes place in a few days.

SPIDER SELF-LIGATING K1

Ø1,5 mm

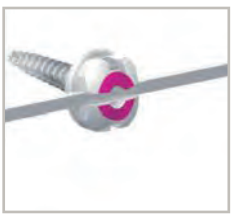
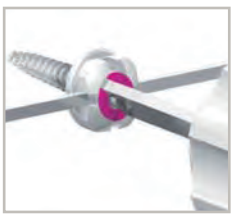
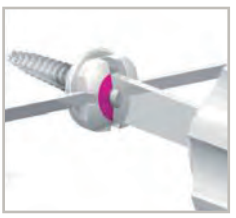
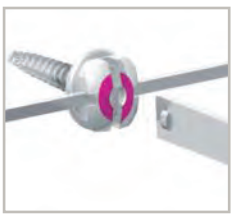
Tapered Thread (Self-tapping / Self-drilling)

Available in length 6,5 – 8 – 10 mm.

The SPIDER SCREW SELF-LIGATING TAD - K1 is self-drilling and self-tapping. Due to the design of the tapered thread, drilling is eliminated in most areas of the mouth. In areas of high bone density, it may be necessary to utilize the Ø 1,1 mm drill provided to penetrate the cortical plate.

During insertion of the Spider K1 do not exceed 20 N/cm.

SXL-1506	Ø 1.5 x 6.5 mm
SXL-1508	Ø 1.5 x 8.0 mm
SXL-1510	Ø 1.5 x 10.0 mm

SPIDER SELF-LIGATING K2

Ø1,9 mm

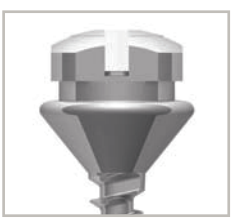
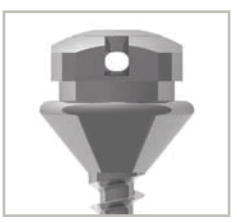
Tapered Thread (Self-tapping / Self-drilling)

Available in length 6 - 7 – 9 – 11 mm.

The SPIDER SCREW SELF-LIGATING TAD - K2 is self-drilling and self-tapping. Due to the design of the tapered thread, drilling is eliminated in most areas of the mouth. In areas of high bone density, it may be necessary to utilize the Ø 1,3 mm drill provided to penetrate the cortical plate.

During insertion of the Spider K2 do not exceed 30 N/cm.

SXL-1906	Ø 1,9 x 6mm
SXL-1907	Ø 1.9 x 7 mm
SXL-1909	Ø 1.9 x 9 mm
SXL-1911	Ø 1.9 x 11 mm

CSS-6008
SELF LIGATING
SPIDER SCREW ORGANIZER

	FSC-1108	DRILL Ø 1,1 mm - K1
	FSC-1309	DRILL Ø 1,3 mm - K2
	DPQ-3420	CONTRA ANGLE PICK-UP DRIVER - SHORT
	DPQ-3425	CONTRA ANGLE PICK-UP DRIVER – LONG
	DLM-3134	DRIVER for closing the slot
	DXL-2820	SELF LIGATING TAD KEY
	DSQ-3424	HANDLE SQUARE DRIVER
	DSP-5652S	PICK-UP DRIVER SHAFT
	DSX-1690S	SCREWDRIVER BODY

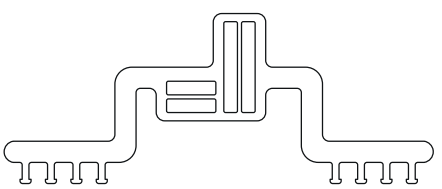
SPIDER LINK

A system of plates for skeletal anchorage

> Allows application of mini-screw in more suitable anatomical areas.
> Easy to place and remove.
> Easy to mould.

SPIDER LINK is a skeletal anchorage system comprising of a SELF-LIGATING SCREW and titanium preformed orthodontic anchorage attachment.
Current skeletal anchorage systems don't always allow the insertion of screws in the desired position, due to teeth interference and/or anatomy.

This new system, SPIDER LINK (SELF-LIGATING SPIDER SCREW + ORTHODONTIC ANCHORAGE ATTACHMENT) lets you overcome this limitation.
The screw can be placed in more suitable anatomical areas and then, thanks to the orthodontic anchorage attachment, it is possible to apply forces to desired teeth.



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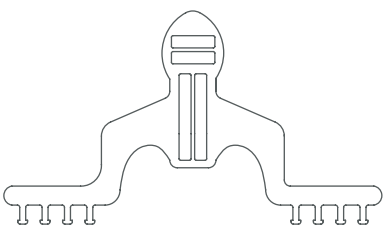

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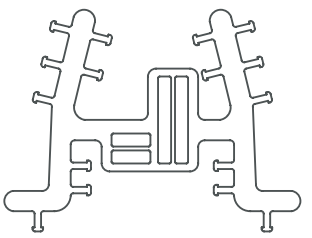
V-FORM



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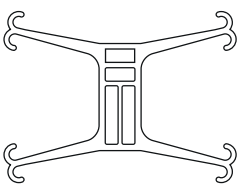

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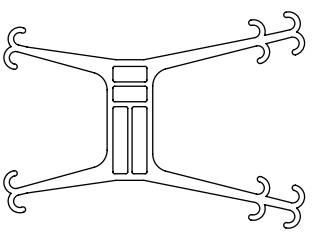

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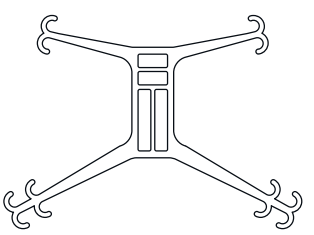
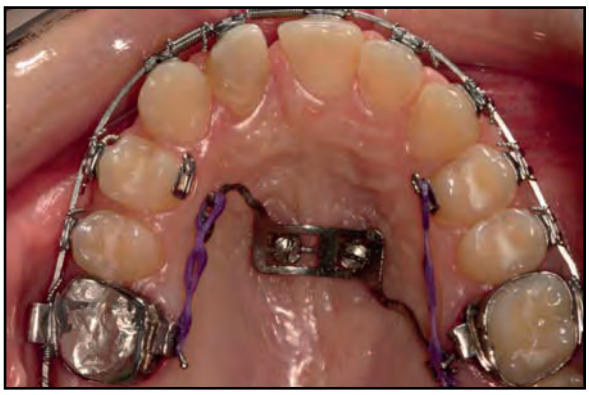
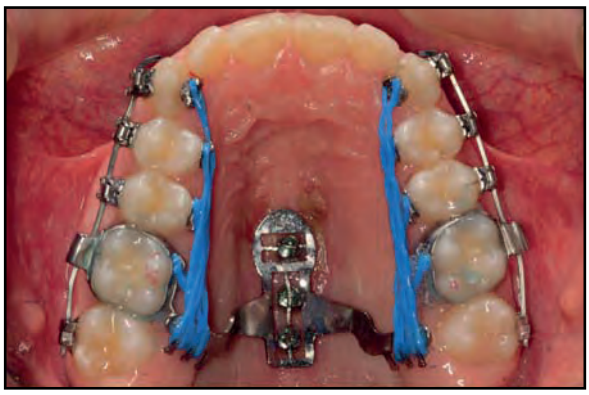


PSLH-0004
H-FORM

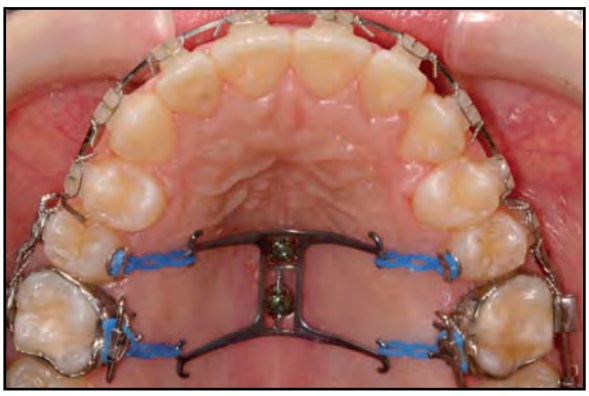
CLINICAL CASES



Orthodontic Anchorage Attachment for molar Mesialization and Distalisation.

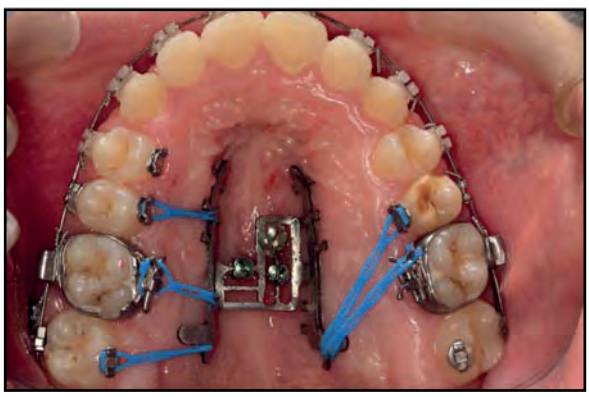


Orthodontic Anchorage Attachment for molar Distalisation.



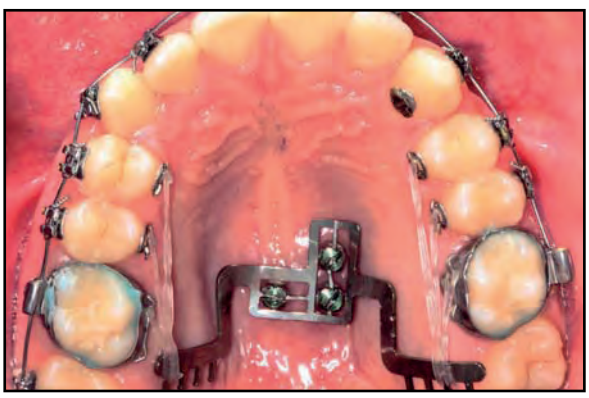
Orthodontic Anchorage Attachment for open bite condition.

Second molars and molars intrusion.



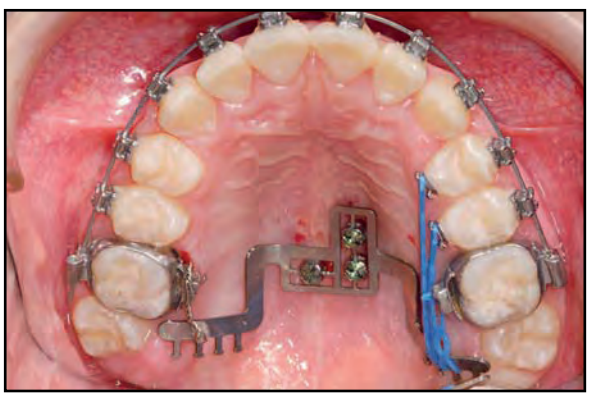
Orthodontic Anchorage Attachment for open bite condition.

Asymmetrical intrusion.



Class II Division 1 crowding treatment

Orthodontic Anchorage Attachment for simultaneous bilateral molar distalisation.



Class II Division 1 on the left side.

Orthodontic Anchorage Attachment for simultaneous molar distalisation.

SPIDER K1

Ø1,5 mm

Tapered Thread (Self-drilling/Self-tapping)

Available in length 6,5 – 8 – 10 mm.

The SPIDER SCREW K1 is self-drilling, due to the design of the tapered thread, drilling is eliminated in most areas of the mouth. In areas of high bone density, it may be necessary to utilize the Ø 1,1 mm drill provided to penetrate the cortical plate. Available in the following versions:

LONG NECK - elongated neck height (2 mm) for areas of thick tissue (Posterior and lateral areas).

SHORT NECK - standard neck height (1 mm) for areas of thin tissue (Anterior and lateral areas).

SCL-1506	Long Neck Ø 1.5 x 6.5 mm
SCL-1508	Long Neck Ø 1.5 x 8.0 mm
SCL-1510	Long Neck Ø 1.5 x 10.0 mm

SCR-1506	Short Neck Ø 1.5 x 6.5 mm
SCR-1508	Short Neck Ø 1.5 x 8.0 mm
SCR-1510	Short Neck Ø 1.5 x 10.0 mm

SPIDER K2

Ø1,9 mm

Tapered Thread (Self-drilling/Self-tapping)

Available in length 6 - 7 - 9 - 11 mm.

The SPIDER SCREW K2 is self–drilling, due to the design of the tapered thread, drilling is eliminated in most areas of the mouth. In areas of high bone density, it may be necessary to utilize the Ø 1,3 mm drill provided to penetrate the cortical plate. The 5 mm and 6 mm lengths screws can be placed in the palate or in areas where the bone thickness is reduced. Available in the following versions:

LONG NECK - elongated neck height (2 mm) for areas of thick tissue (Posterior and lateral areas).

SHORT NECK - standard neck height (1 mm) for areas of thin tissue (Anterior and lateral areas).

SCL-1906	Long Neck Ø 1.9 x 6.0 mm
SCL-1907	Long Neck Ø 1.9 x 7.0 mm
SCL-1909	Long Neck Ø 1.9 x 9.0 mm
SCL-1911	Long Neck Ø 1.9 x 11.0 mm

SCR-1906	Short Neck Ø 1.9 x 6.0 mm
SCR-1907	Short Neck Ø 1.9 x 7.0 mm
SCR-1909	Short Neck Ø 1.9 x 9.0 mm
SCR-1911	Short Neck Ø 1.9 x 11.0 mm

SPIDER C1

Ø1,5 mm

Cylindrical Thread (Pre-drilling/Self-tapping)

Available in length 6,5 – 8 – 10 mm.

The SPIDER SCREW C1 is self–tapping and requires pre-drilling with a drill of diameter 1,2 mm. Available in the following versions:

LONG NECK - elongated neck height (2 mm) for areas of thick tissue (Posterior and lateral areas).

SHORT NECK - standard neck height (1 mm) for areas of thin tissue (Anterior and lateral areas).

SLP-1506	Long Neck Ø 1.5 x 6.5 mm
SLP-1508	Long Neck Ø 1.5 x 8.0 mm
SLP-1510	Long Neck Ø 1.5 x 10.0 mm

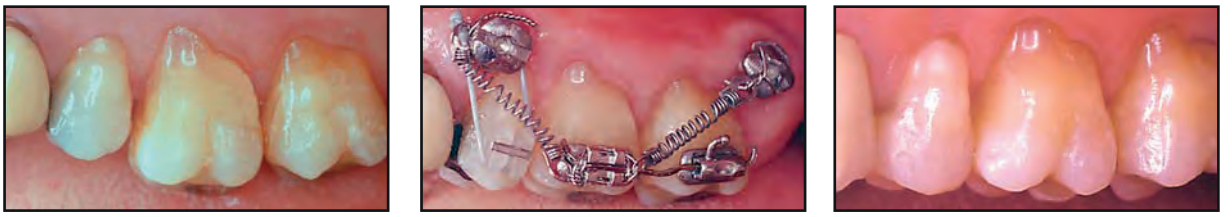
SSM-1506	Short Neck Ø 1.5 x 6.5 mm
SSM-1508	Short Neck Ø 1.5 x 8.0 mm
SSM-1510	Short Neck Ø 1.5 x 10.0 mm

CSS-4009

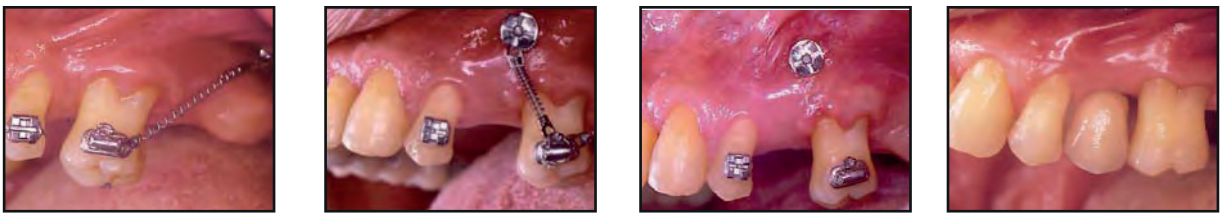
SPIDER SCREW ORGANIZER

	FSC-1210	DRILL Ø 1.2 mm - C1
	FSC-1108	DRILL Ø 1.1 mm - K1
	FSC-1309	DRILL Ø1.3 mm - K2
	DPQ-2820	CONTRA ANGLE PICK-UP DRIVER – SHORT
	DPQ-2825	CONTRA ANGLE PICK-UP DRIVER – LONG
	DPX-2830	CONTRA ANGLE CROSS DRIVER
	DSQ-2824	HANDLE DRIVER SHORT
	DPH-2824	PICK-UP HANDLE DRIVER
	DSX-2852S	CROSS DRIVER SHAFT for DSX-1690S
	DSP-5052S	PICK-UP DRIVER SHAFT for DSX-1690S
	DSX-1690S	SCREWDRIVER BODY

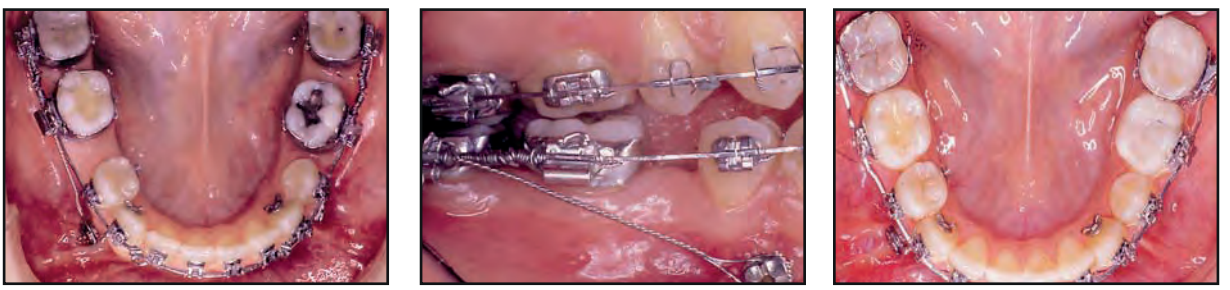
CLINICAL CASES



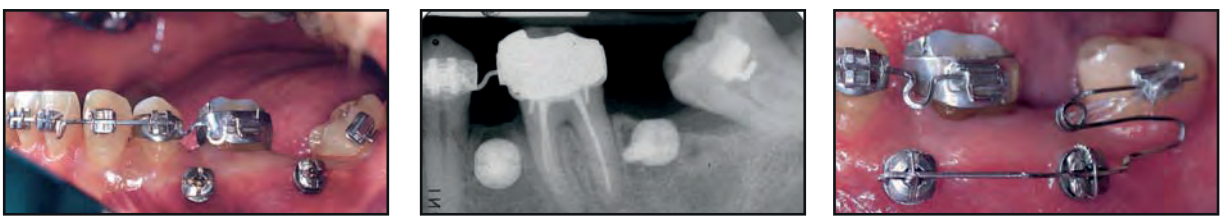
Intrusion Posterior Areas



Direct Anchorage – Molar Uprighting and Intrusion



Indirect Anchorage (by kind permission of Dr. B.G. Maino)



Molar Uprighting and Intrusion (by kind permission of Dr. N.Derton)

SPIDER PIN

Ø 1,3 mm

Cylindrical thread (Self-Tapping)

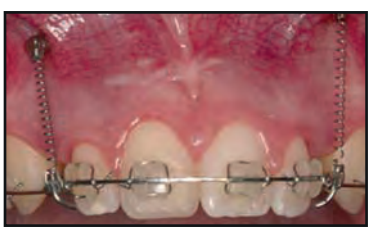
Available in length 8 – 10 mm.

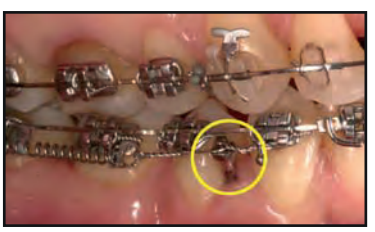
SPIDER PIN is a simple design Self-Tapping screw and requires pre-drilling. It is ideal for areas where a reduced size head is required (i.e. narrow inter-proximal spaces). The Spider PIN head is rounded to increase patient comfort and allow for better cleaning.

- Ideal for narrow interproximal spaces.
- Simple head, perfect for NiTi closed coil spring attachments or elastic chains.
- Requires no patient cooperation and reduces treatment time.
- Smooth, rounded design for patient comfort.

SCL-1308	Ø 1.3 x 8.0 mm
SCL-1310	Ø 1.3 x 10.0 mm

CLINICAL CASE





Spider Pin Application

CSS-3006
SPIDER PIN ORGANIZER

	FSC-0910	DRILL - PIN
	DPQ-2322	CONTRA ANGLE PICK-UP DRIVER
	DSQ-2324	HANDLE DRIVER – SHORT
	DSP-2352S	PICK-UP DRIVER SHAFT for DSX-1690S or DST-1600
	DSX-1690S	SCREWDRIVER BODY

OPTIONAL DEVICES WORKING WITH ALL SYSTEMS

	CAM-2000	MANUAL CONTRANGLE
	DST-1600	TORQUE DRIVER

- Torque driver to control insertion force.
- The torque driver has a range of torque of 15 N/cm: from 5 up to 20 N/cm.
- Interchangeable shafts for all kind of Spider Screw.
- Can be sterilized.

SUMODIS

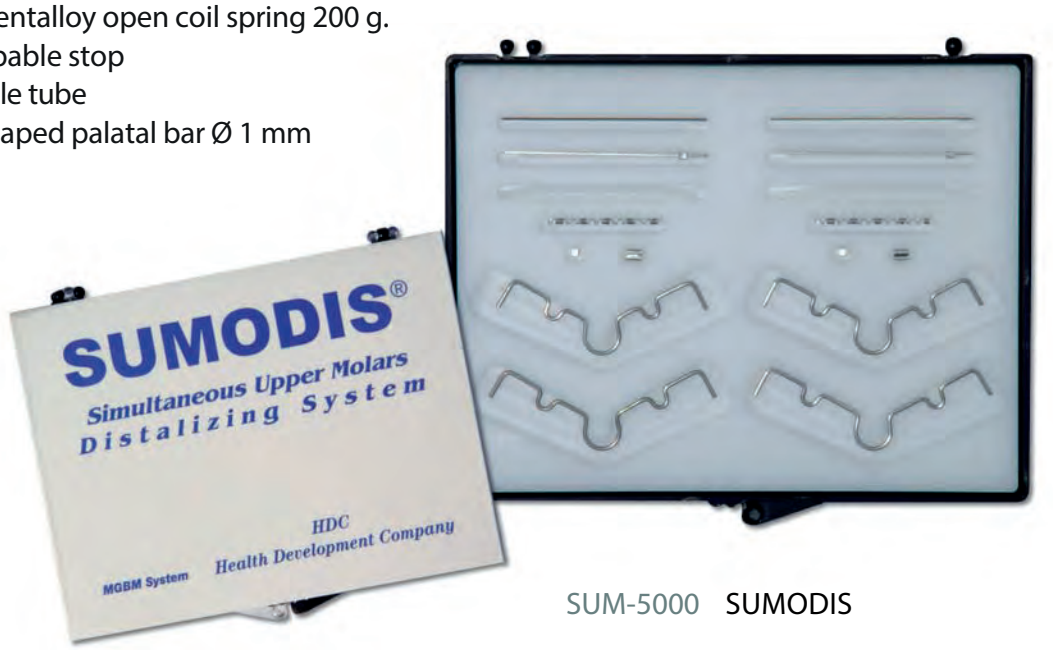
Simultaneous upper Molars Distalizing System

SUMODIS it's a system for simultaneous distalization of upper molars in presence of second molars in II class non-extractive treatments without co-operation.

SUMODIS is a combination of sliding mechanics using Spider Screws as a sole anchorage resource.

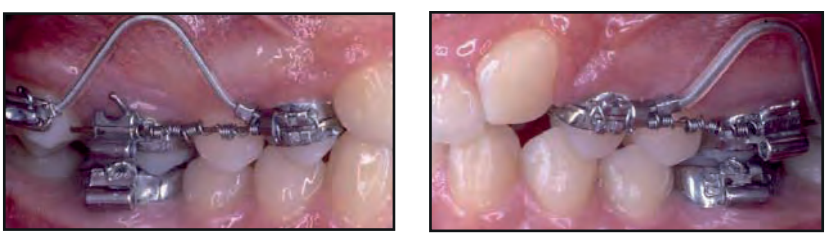
SUMODIS (Simultaneous Upper Molar Distalizing System) main characteristic is two distalizing components: one against the first molar and the other one against the second, working simultaneously.

One Kit Sumodis contains:
Stainless steel tempered wire .016x.022
Neosentalloy wire .018x.025 provided with stop
Protection elastomer tube
Neosentalloy open coil spring 200 g.
Crimpable stop
Double tube
Preshaped palatal bar Ø 1 mm

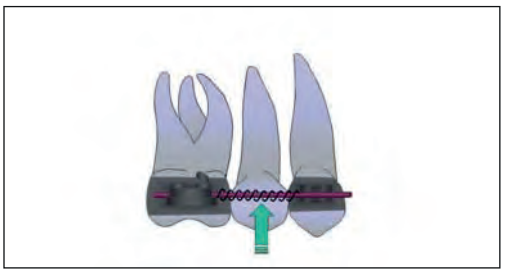


SUM-5000 SUMODIS

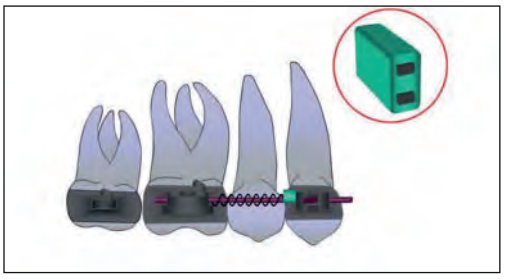
CLINICAL CASE



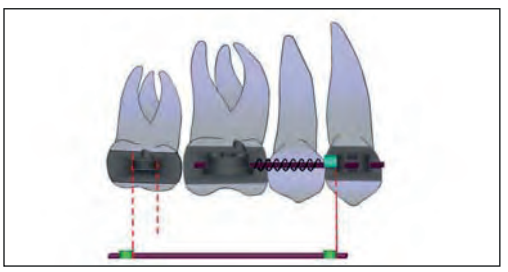
Sumodis in place



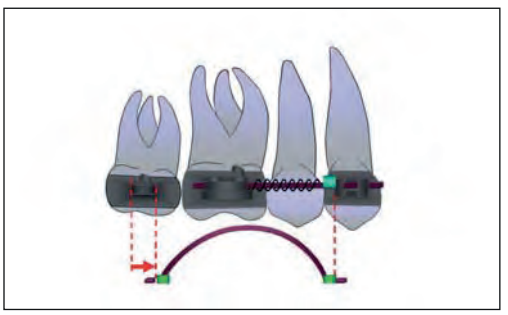
First distalizing component. Insert in a sectional .016'' x .022'' stainless steel wire and a 200 g. NeoSentalloy open coil between the first premolar and the molar.



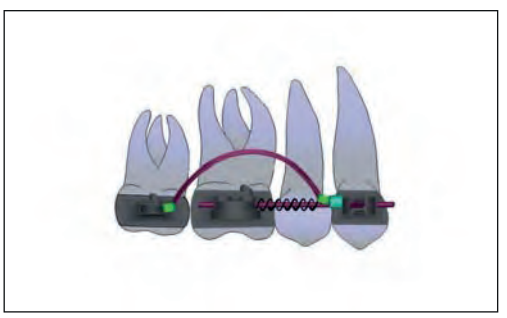
Before fixing .016'' x .022'' stainless steel wire, insert the double tube into it using the lower tube and position it near by the premolar bracket. The double tube, which can slide, is blocked by the compressed coil on one side and the premolar bracket on the other side.



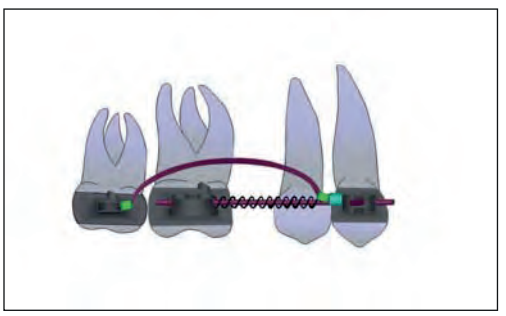
The second distalizing component is a shape memory .018'' x .025'' stainless steel NeoSentalloy wire (with crimped stop).
Put the second stop at a distance of 6 mm longer than the distance between the mesial side of the buccal tube on the second molar and the distal side of the double tube on the sectional wire.



When the NeoSentalloy wire is inserted into the tube on the second molar and in the double tube free hole, it will raise in the buccal fold and activate 6 mm.



In this phase you can see both distalizing components simoultaneosly activated.



End of first phase MBGM system. Molars Distalization done.

SPIDER K2 REGULAR PLUS

Ø 2 mm

Cylindrical Thread (Self-drilling)

Available in length 6 – 7 – 9 – 11 – 13 – 15 mm.

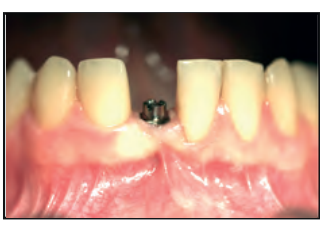
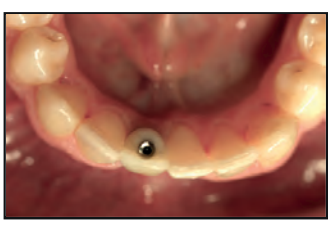
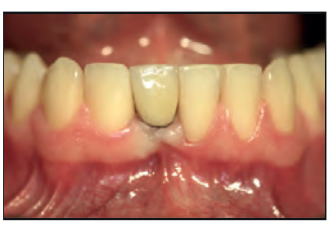
The inner threaded portion of the SPIDER SCREW K2 REGULAR PLUS opens up vast possibilities for applications.
Additional devices can be fitted to the screw, such as acrylic resin abutments, stainless steel abutments, pre-shaped abutments or lab made units.

The palatal insertion of the SPIDER SCREW K2 REGULAR PLUS and the possibility of preparing specific orthodontic devices attachable to it allows an innovative way of treating class II and class III conditions, reducing treatment time and requiring no patient co-operation.

SSP-2006	Regular Plus Ø 2 x 6.0 mm
SSP-2007	Regular Plus Ø 2 x 7.0 mm
SSP-2009	Regular Plus Ø 2 x 9.0 mm
SSP-2011	Regular Plus Ø 2 x 11.0 mm
SSP-2013	Regular Plus Ø 2 x 13.0 mm
SSP-2015	Regular Plus Ø 2 x 15.0 mm

CLINICAL CASES

1.

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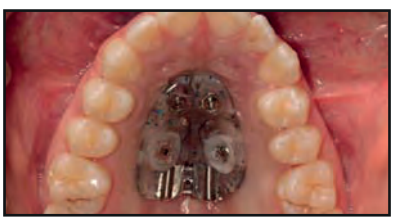
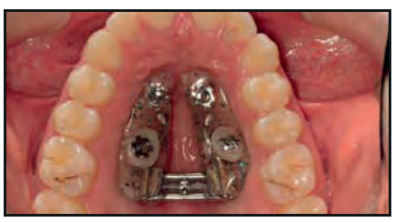
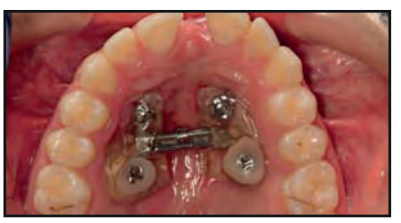

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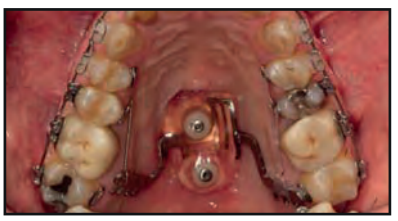
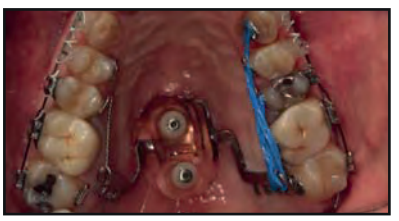

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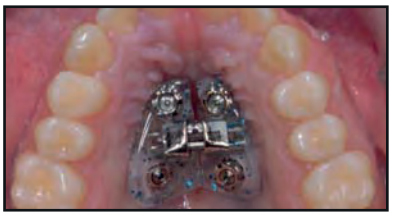

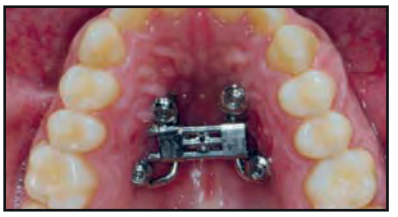

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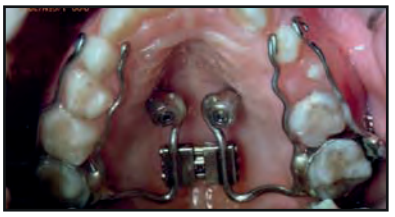
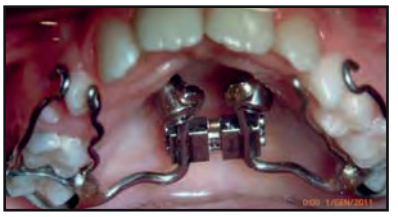




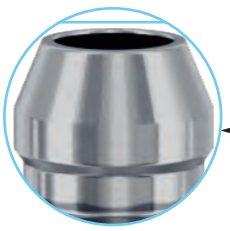
By kind permission of Dr. B.G. Maino

	FSC-1319	LONG DRILL Ø 1,3 MM - RP
	PMA-5008	ACRYLIC RESIN ABUTMENT
	PMA-4050R	STAINLESS STEEL ABUTMENT
	PMA-5006R	UTILITY ABUTMENT
	CTS-5000	COPING TRANSER
	ANR-4012	LAB ANALOG
	DSE-2410	DRIVER
	DSX-1690S	SCREWDRIVER BODY

SPIDER SCREW

Regular Plus KONIC

ORTHODONTIC HEAD

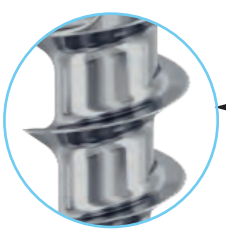


The Cylindrical head is designed to overcome possible disparallelisms between the screw inclination and the customized appliance to be used.

TRANSMUCOSAL PORTION

The transmucosal portion is polished with a special treatment for an excellent bonding to the oral mucosa and to help avoid soft tissue irritation.

THREADING



The asymmetric thread profile is specifically studied to provide an optimal screw stability and an easier screw insertion.

TIP

Conic Flute.
The Spider Screw's tip shape makes it easy to place it and to maintain the inclination angle required.

SPIDER SCREW
Regular Plus KONIC

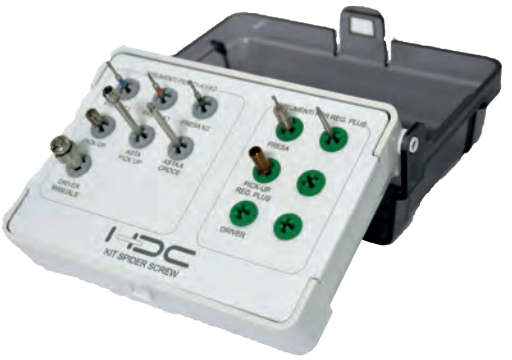
FSC-1309G DRILL FOR SSP Ø 2,0 mm

FSC-1609L DRILL FOR SSP Ø 2,3 mm

DPQ-3825 PICK-UP DRIVER FOR GUIDED SURGERY

PRL-3513 DRILL EXTENSION

DPM-3075 CONTRA ANGLE PICK-UP DRIVER



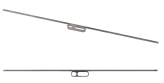
CSS-7014 SPIDER SCREW Regular Plus Kit

BGU-6050 SURGICAL GUIDE TUBE

TUB-1001 MESIAL TUBE WITH HOOK

TUB-1003 MESIAL TUBE WITHOUT HOOK

PSRP-1001N WIRE SUPPORT RING



PSRP-2005N PLATE WITH WIRE

VRS-1650 FIXATION SCREW FOR PLATE AND RING

SCREW LENGTHS Ø 2,0 mm

SSP-2007N Regular Plus Ø 2 x 7 mm
SSP-2008N Regular Plus Ø 2 x 8 mm
SSP-2009N Regular Plus Ø 2 x 9 mm
SSP-2010N Regular Plus Ø 2 x 10 mm
SSP-2011N Regular Plus Ø 2 x 11 mm
SSP-2012N Regular Plus Ø 2 x 12 mm
SSP-2013N Regular Plus Ø 2 x 13 mm
SSP-2014N Regular Plus Ø 2 x 14 mm
SSP-2015N Regular Plus Ø 2 x 15 mm

SCREW LENGTHS Ø 2,3 mm

SSP-2307N Regular Plus Ø 2,3 x 7 mm
SSP-2308N Regular Plus Ø 2,3 x 8 mm
SSP-2309N Regular Plus Ø 2,3 x 9 mm
SSP-2310N Regular Plus Ø 2,3 x 10 mm
SSP-2311N Regular Plus Ø 2,3 x 11 mm
SSP-2312N Regular Plus Ø 2,3 x 12 mm
SSP-2313N Regular Plus Ø 2,3 x 13 mm
SSP-2314N Regular Plus Ø 2,3 x 14 mrn
SSP-2315N Regular Plus Ø 2,3 x 15 mm

COMPONENTS

STT-3016 SPRING STOP

PSRP-2001N PLATE

DSQ-2507 DRIVER

ANR-3812 REGULAR PLUS ANALOG

PMA-3850 STAINLESS STEEL ABUTMENT

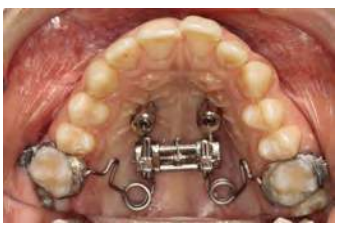
CTS-6000 COPING TRANSFER

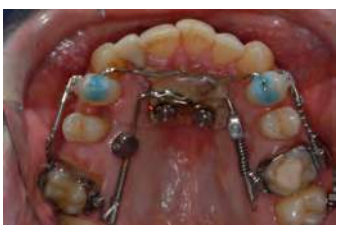
SCB-5010 SCANBODY

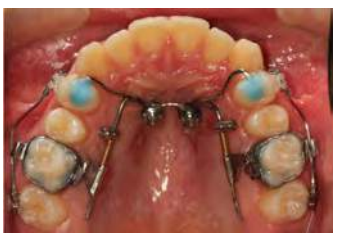
SRP-3850 NITI SPRING 500 GR

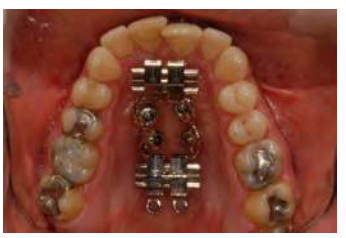
VRS- 1645 ABUTMENT FIXATION SCREW

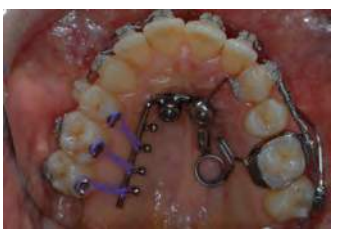
By kind permission of Dr. B.G. Maino Partner Lab: Orthomodul, CDT Emanuele Paoletto

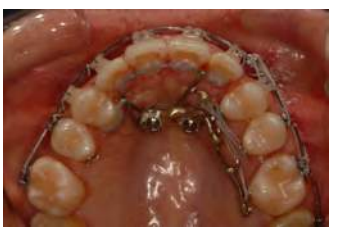












rev. mar. 2017

HDC S.r.l.
Via dei Mestieri 5/7, Thiene 36016 (VI) Italy
Tel. +39 0445 364148
info@hdc-italy.com

CERTIFICATIONS

HDC obtained CE marking and ISO 13485, which prove that our product has been assessed and meets EU safety, health and environmental protection requirements, as well as the requirements for a comprehensive quality management system for the design and manufacture of medical devices.

Certificato

kiwa
Partner for progress

Reg. Numero 9950- M
Data di rilascio 2012-06-29 Data di ultima modifica 2015-06-25
Data di prossimo rinnovo 2018-06-28

Certificato del Sistema di Gestione per la qualità
ISO 13485:2003

Si dichiara che il sistema di gestione per la Qualità dell'Organizzazione:

H.D.C. S.r.l.

è conforme alla norma UNI CEI EN ISO 13485:2012 per i seguenti prodotti/servizi:

Progettazione e produzione di viti ortodontiche, impianti dentali e relativi accessori.
Commercializzazione di prodotti per il settore ortodontico

Chief Operating Officer
Giampiero Belcredi

Il mantenimento della certificazione è soggetto a sorveglianza annuale e subordinato al rispetto dei requisiti contrattuali Kiwa Cermet Italia.

Rifersi al manuale qualità per i dettagli delle esclusioni ai requisiti della norma UNI CEI EN ISO 13485:2012
Il presente certificato è costituito da 1 pagina.

H.D.C. S.r.l.
Via Asiago, 44
36030 Sarcedo VI Italia

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel. +39.051.459.3.111
Fax +39.051.763.352
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

IAF

ACCREDIA
CERTIFICATO N. 0476
SGQ N° 007A SSI N° 006G
SGA N° 016D FSN N° 004I
PRD N° 066B

CERTIFICATO CE DEL SISTEMA DI GARANZIA DELLA QUALITÀ

EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione:
We certify that, on the basis of audit carried out, the full Quality Assurance System of the Company:

H.D.C. S.r.l.

Reg. No: MED 9911-A

Indirizzo / Address:

Unità Operativa / Operational unit:
Via Asiago, 44
36030 Sarcedo, VI - Italia

Sede legale / Registered headquarter
Via dell'Industria, 19
Sarcedo (VI) , VI - Italia

È conforme ai requisiti applicabili della / *Is in compliance with the applicable requirements of:*

Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni
93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended

per le seguenti tipologie di Dispositivi Medici / *for the following Medical Devices:*

Componentistica protesica e accessori / *Prosthetic components and accessories*
Frese e strumentario odontoiatrico / *Drills and dental equipment*
Impianti dentali / *Dental implants*

Identificazione / Identification: Vedere allegato tecnico al presente Certificato / *See technical sheet enclosed to this certificate*

Il presente Certificato è soggetto al rispetto del Regolamento CERMET ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza.
L'allegato tecnico è parte integrante del presente Certificato.
This Certificate is subject to CERMET regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.
The technical sheet is an integrating part of this Certificate.

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European Notified Body n. 0476

member of group kiwa
Partner for progress

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Certificazione e ricerca per la qualità

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