Instructions for use

ORTHODONTIC SCREWS

1. **PRODUCT**

SPIDER SCREW ORTHODONTIC SCREWS
The HDC Spider Screw System includes a series of self-tapping endosseous screws of different designs and sizes for specific applications in the orthodontic field. The screw is an anchorage device for orthodontic and pre-prosthetic applications that facilitates tooth movement. Spider Screw is clean, decontaminated, and sterilized with gamma rays, ready for use. Accessories are sold NON-STERILE and must be sterilized before use. The HDC Spider Screw is made of titanium alloy, a highly biocompatible material supplied by internationally certified companies. The device is for temporary use and must be removed after orthodontic treatment.

Chemical composition of te raw material

Titanium Grade 5 - Ti 6 AL 4V-ELI, ISO 5832-3 and ASTM F 136

Element	Maximum composition limits Mass fraction in percent %
Alluminium	6,09
Vanadium	3,98
Iron	0,16
Oxigen	0,11
Carbon	0,01
Nitrogen	0,01
Hydrogen	0,02
Titanium	Balance

2. **Instructions for Use:**

Step 1

Check the label for the type of screw, diameter, length, and sterilization expiration date. This information, along with the lot number, must be transferred to the patient's medical record using the adhesive label inside the package.

Step 2

Open te box and remove the blister pack from inside. If the blister pack is damaged, its content may have lost its sterility and therefore must not be used. The operator must use sterile gloves.

Step 3

Remove the inner container holding the Spider Screw and place it on the surgical tray.

Step 4

Unscrew the cap to expose the screw in its housing.

Step 5

Bone insertion
HDC screws are self-drilling and self-tapping and can therefore be inserted without pre-drilling the bone, if this is not very compact. In order to avoid possible screw breakage, bone drilling is still recommended, especially in the presence of compact bone, in the mandible and when using longer screws with a larger diameter (K2), using our FSC-1108 drills for the Spider Screw K1; FSC-1309 for the Spider Screw K2. The Spider Screw C1 must be inserted after drilling the hole using the FSC-1210 drill. In some cases, pre-drilling can be avoided depending on the quality of the bone (in the case of less compact bone). The Spider Screw PIN must be inserted after drilling the hole using the FSC-0910 drill bit. In some cases, pre-drilling can be avoided depending on the quality of the bone (in cases of low bone density).
If you use a drill to pre-drill the hole, it is not necessary to use the entire length of the drill bit: a 2-3 mm hole (the size needed to penetrate the cortical bone) is more than enough in most cases.

Spider Screw K1-K2- C1 – SL (ref code: SSL)
Manual insertion: Using the DSP-5052S + DSX-1690S manual pick-up rod, remove the screw from its housing and transfer it to the appropriately prepared site. During insertion, to avoid excessive torque, it is advisable to alternate between screwing and unscrewing. During insertion, it is recommended not to apply too much pressure, as this could cause the tip to break.
Insertion with contra-angle handpiece: Using the DPQ-2820 connected to the low-speed handpiece (20-40 rpm), remove the screw from its housing and transfer it to the appropriately prepared site. The insertion force must not exceed 20 N/cm (30 N/cm for K2).

Spider Screw PIN

Manual insertion: Using the manual pick-up shaft DSP-2352S + DSX-1690S or DST-1600, remove the screw from its housing and transfer it to the appropriately prepared site. The insertion force must not exceed 15 N/cm.
Insertion with contra-angle: Using the driver DPQ-2322 for the Spider Screw PIN connected to the low-speed handpiece (20-40 rpm), remove the screw from its housing and transfer it to the appropriately prepared site. The insertion force must not exceed 15 N/cm.

Spider Screw Regular Plus + Konic

The Spider Screw Regular Plus can also be inserted without pre-drilling the bone if it is not very compact. However, as the screw has a diameter of 2 mm, in order to avoid possible screw breakage, we recommend drilling the bone, especially in the case of compact bone or in the mandible, using our FSC-1309 drill.
Manual insertion: Using the Pick-Up DSP-5052S + Driver DSX-1690S or DST-1600, remove the screw from its housing and transfer it to the appropriately prepared site.
Insertion with contra-angle: using the DPQ-2820 (Regular Plus) or DPQ-3825 (Regular Plus Konic) driver connected to the low-speed handpiece (20-40 rpm). Remove the Regular Plus Spider Screw from its housing and transfer it to the appropriately prepared site. The insertion force must not exceed 30 N/cm. For the use of the Konic spider with digital planning, refer to the Spider Screw catalog, which can be downloaded from the website www.hdc-italy.com.

Spider Screw SL K1 e SL K2 (codice SXL)

Manual insertion: Using the DSP-5652S + DSX-1690S manual pick-up driver or DST-1600 + DSP-5652S torque driver, remove the screw from its housing and transfer it to the appropriately prepared site. During insertion, to avoid excessive torque, it is advisable to alternate between screwing and unscrewing phases. During the insertion phase, it is recommended not to exert too much pressure, which could cause the tip to break.

Insertion with contra-angle: Using the DPQ-3420 connected to the low-speed handpiece (20-40 rpm), remove the screw from its housing and transfer it to the appropriately prepared site. The insertion force must not exceed 20 N/cm (30 N/cm for SL K2).

Step 6

Spider Screw K1-K2-C1

For final positioning adjustment, use either the DSQ-2824 or DSX-1690S + DSX-2852S driver at your discretion.

Spider Screw PIN

to adjust the final position, use the DSQ-2324 driver at your discretion

Spider Screw Self-Ligating K1 e Self-Ligating K2

To adjust the final position, use the DSQ-3424 driver at your discretion.

After insertion, the Spider Screw Self-Ligating appears as shown in fig. 1. It is possible to insert . 018''x.022 or 018''x.025 orthodontic wires (fig. 2). To secure rectangular wires or other orthodontic devices of the same size, insert the DXL-2820 manual driver into the head slot and rotate the insert to lock the wire in place (Fig. 3). The insert can be rotated up to a maximum of 90°.

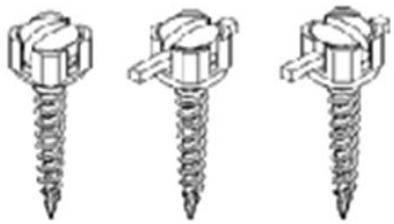

Fig.1 Fig.2 Fig.3

Step 7

Loading
Spider Screw can be loaded immediately after insertion. Forces ranging from 50g to 300g can be applied depending on bone quality and the desired orthodontic movement. The loaded force must never exceed 300g. It is recommended to initially apply a force of 50g and increase the force during orthodontic treatment.

3. **Contraindications**

-Insufficient quantity and/or poor quality of bone;
-Poor oral hygiene;
-Heavy smoking, tobacco, and alcohol abuse;
-Systemic blood diseases;
-Uncontrolled diabetes.

4. **Recommendations**

The application of surgical screws is a procedure that requires specific knowledge of anatomy and technique, and must therefore be performed by specifically trained personnel. It should be noted that improper patient selection and/or incorrect technique may result in failure of the procedure and/or loss of supporting bone substance. Once used, screws must not be reused. Any screw that has been contaminated with blood or any bodily fluid must be discarded.

5. **Warnings**

The screws have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifacts in the MR environment. The safety of the screws in the MR environment is unknown. Scanning a patient with this device may cause injury to the patient.
For correct and safe use of this device, it is recommended to use HDC instruments and/or connection devices. HDC declines all responsibility for the use of its devices with instruments and/or in connection with other brands.

6. **Attention**

The DEVICE IS FOR SINGLE USE ONLY and its reuse, in addition to being unsuitable for its intended use, could lead to serious infections, with loss of the implant and possible bone necrosis. The use of these products is restricted exclusively to qualified dentists and surgeons. Do not use if the outer packaging or inner wrapping is open or damaged. The surgical line is subject to continuous evolution.

7. **Packaging**

The Spider Screw HDC is packaged in double packaging that guarantees its sterility until it is removed for insertion in the oral cavity.

8. **Storage**

Store the device as to avoid damage to the packaging. Store at room temperature in a dry place. The expiry date refers to the product in its intact packaging. Do not use the device if the packaging is damaged.

9. **Intended Use**

Orthodontic anchorage device. Use in orthodontics and dentistry.

10. **Precautions for use**

An effective and comprehensive screening of the implant candidate must be performed. Careful examinations, panoramic and periapical radiographs are essential for the precise determination of anatomical references, occlusal conditions, periodontal status, and bone adequacy. Lateral cephalometric radiographs, CT scans, and tomograms may also be beneficial.

11. **Caution**

Affix the self-adhesive sticker provided in the package to the patient's medical record, indicating the location where the device was inserted to enable traceability of the product to the end user, THE PATIENT.

12. **Information for te Patient**

Follow a thorough oral hygiene routine at home. Undergo specialist check-ups if you experience even the slightest local discomfort at the site of the device.

13. **Collateral Effects**

After application of the Spider Screw, premature anchorage loss may occur. Potential causes include, but are not limited to:
- Insufficient bone quantity and/or quality, osteoporosis, osteolysis, osteomyelitis, inhibited revascularization, or infection may cause loosening, bending, cracking, or fracture of the device or premature loss of bone fixation, resulting in failure to union.
- Infections.
- Poor oral hygiene or patient cooperation and/or genetic diseases (diabetes).

- Migration, bending, fracture, or loosening of the screw.
- Metal sensitivity or allergic reaction to a foreign body.
- Pain, discomfort, or abnormal sensation due to the presence of the device.
- Increased fibrous tissue response around the fracture site and/or screw.
- Bone necrosis.
- Inadequate healing.
- Localized swelling, edema, and tissue reaction.

In addition to these adverse effects, there are always possible complications of any surgical procedure, including, but not limited to: infections, nerve damage, and pain that may not be related to the screw.
There are no pharmacological side effects as no substances are released from the device. Side effects such as edema, paresthesia, infection, and dehiscence may occur, but these are not due to the shape or material of the device but to improper surgical technique.

14. Information for proper operation

This medical device must not be reused. Reuse may cause cross-contamination, irritation, and infection, as well as breakage. In such cases, the manufacturer declines all responsibility.
Sterility is guaranteed until the packaging is broken or damaged.

15. Disposal

The devices are used in hospital environment and must therefore be disposed of in accordance with the laws in force regarding waste disposal and applied by the hospital facility. In particular, used devices, which may be polluted and biologically contaminated, must be disposed of as special waste. As they are intended for use in hospital environment that normally implement this special collection, it is not necessary to provide such information on the label.
Any serious incident involving the medical device supplied by us must be reported to the Manufacturer, the Notified Body, and the Competent Authority of the Member State in which you are based.
The summary of safety and clinical performance is available on EUDAMED and, until this platform is fully operational, can be requested from H.D.C. s.r.l. by sending an email to info@hdc-italy.com. (base UDI-DI : 805701314spiderscrewCJ and 805701314smartscrewU2)
Glossary of symbols

	Manufacturer	Indicates the medical device manufacturer., as written in te directive UE 90/385/CEE, 93/42/CEE and 98/79/CE.
	Date of manufacture	IIndicates the date when the medical device was manufactured.Data format: YYYY-MM-D
	Use by	Indicates the date after which the medical device is not to be used. Data format: YYYY-MM-DD
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue or model number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	Do not use if package is damaged and consult instructions for use.	Indicates a medical device that should not be used if the package has been damaged or opened.
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

	Do not resterilize	Indicates a medical device that is not to be resterilized
 Www.hdc-italy.com/ifu	consult instructions for use	Informs the user of the need to consult the instructions for use and where the instructions for use in electronic format (eIFU) and the symbol glossary can be found.
	Caution: Read all warnings and precautions in instructions for use	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
 0425	CE marking	Signifies European technical conformity with the identification number of the Notified Body for class IIa, IIb, III medical devices
	Medical device	Indicates the item is a medical device
	Prescription only	Requires prescription in the United States.
	Double sterile barrier system	Indicates a Double sterile barrier system

H.D.C s.r.l.

Via dei Mestieri 5-7 36016 - Thiene (VI) - ITALY

Tel. 0445 364148 E-mail: info@hdc-italy.com