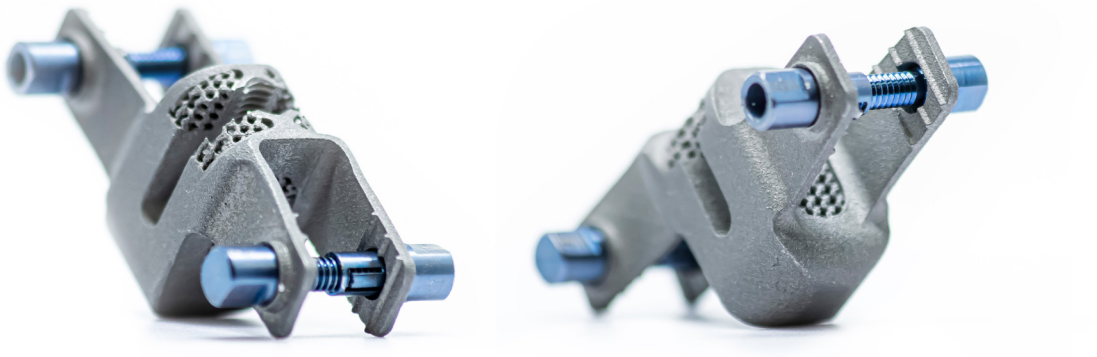
evo



Product photo

Manufacturing company	▪ Clover Orthopedics s.r.l.
Distributor company	▪ Clover Orthopedics s.r.l.
Trading name	▪ EVO - ISD

Product type

The ISD system consists of a trabecular interspinous device and two locking knurled pins. ISD is an interspinous lumbar stabilization device used to promote fusion of the spine (L1-S1) when used in combination with bone / bone substitutes.

Materials

- Implantable Titanium
- Ti6Al4V Implantable Titanium Alloy

Indications

ISD is designed to anchor to the spinous processes (L1-S1) with the aim of stabilizing and promoting fusion of the posterior column of the UFR (functional unit of the spine), when used in combination of bone / bone substitutes, in the conditions of spondyle disc osteoarthritis of the lumbar spine, degenerative facet joint disease, spinal canal stenosis. Any surgical decisions other than those recommended by the manufacturer are at the discretion and responsibility of the surgeon. For more information, see the instructions for use of the device in question.

Controindicazioni

Contraindications of the ISD system include, but are not limited to:

Absolute contraindications

- Stabilization and fusion without bone grafting
- Any medical or surgical conditions that could preclude benefits spinal surgery;
- Infections in the active phase;
- Previous history of allergy to any of the components of the ISD device;
- Previous history of metabolic bone diseases;
- Patients who are not cooperating and unable to follow the prescriptions;
- Not complete development of the osteo-skeletal system;
- Patient undergoing immune-suppressive therapy.

Relative contraindications

- Metastases;
- Severe muscular, neurological or vascular diseases;
- Fever or leukocytosis;
- Pregnancy;
- Signs of inflammation in the implant site;
- Inadequate soft tissue coverage at the surgery site.

Contraindications to be evaluated at the surgeon's discretion based on the clinical and anatomical picture of the patient:

- Grade > 1 spondylolisthesis and unstable spondylolisthesis;
- Degenerative lumbar scoliosis with Cobb angle> 25 °;
- Previous history of osteopenia, osteoporosis and osteomalacia;
- Previous decompressive laminectomy, hemilaminectomy at the level to be operated on, as it is possible that the spinous process is weakened;
- Radiographically compromised vertebral bodies at the lumbar level (s) to be operated on due to trauma or tumor (eg compression fracture);

If the Clover Othopedics ISD device is deemed to be the best solution for the patient, but the patient has one or more of the aforementioned contraindications, it is essential that the patient is informed of the adverse consequences that could hinder the success of the surgical procedure. For more information, see the instructions for use of the device in question.

Product features

- The system consists of a series of implantable titanium spacers having different sizes, made using "3D Printing" technology.
- The single spacer is characterized by a hollow central part obtained as combination of a "monolithic" part and a "trabecular" part, presents a hollow in the front (to allow a conspicuous bone graft / bone substitute) and the elongated and rounded back to facilitate insertion in situ.
- At both ends there are two easily modelable thin wings that allow the device, through the use of a fixing pin made of implantable titanium alloy, to be firmly attached to the prickles.
- The use of 3D Printing as the manufacturing technology of the spacers allows to obtain:
  - A coarse surface finish, characterized by a high roughness.
  - The central trabecular part.

  These two characteristics favor the fusion and osseointegration process of the device.

Packaging and sterilization

- The system is washed and packaged inside a double sealed PE + Tyvek medical bag suitable for ETO sterilization.

Brand

- Clover Orthopedics

Class

- IIb

Certifications

- CE mark (0426)

CE

SISTEMA DI GESTIONE QUALITÀ CERTIFICATO
ITALCERT
UNI CEI EN ISO 13485:2016
UNI EN ISO 9001:2015

CND	RDM	CODE	DESCRIPTION
K0103 - DEVICES FOR MINI-INVASIVE SPINAL SURGERY	2014827	ISD-A00TT00008	EVO – SPACER H8 with locking pin
K0103 - DEVICES FOR MINI-INVASIVE SPINAL SURGERY	2014839	ISD-A00TT00010	EVO - SPACER H10 with locking pin
K0103 - DEVICES FOR MINI-INVASIVE SPINAL SURGERY	2014843	ISD-A00TT00012	EVO - SPACER H12 with locking pin
K0103 - DEVICES FOR MINI-INVASIVE SPINAL SURGERY	2014844	ISD-A00TT00014	EVO - SPACER H14 with locking pin
K0103 - DEVICES FOR MINI-INVASIVE SPINAL SURGERY	2014846	ISD-A00TT00016	EVO - SPACER H16 with locking pin
K0103 - DEVICES FOR MINI-INVASIVE SPINAL SURGERY	2051553/R	ISD-A10TT00008	EVO – AXIAL SPACER H8 with locking pin
K0103 - DEVICES FOR MINI-INVASIVE SPINAL SURGERY	2051554/R	ISD-A10TT00010	EVO – AXIAL SPACER H10 with locking pin
K0103 - DEVICES FOR MINI-INVASIVE SPINAL SURGERY	2051555/R	ISD-A10TT00012	EVO – AXIAL SPACER H12 with locking pin
K0103 - DEVICES FOR MINI-INVASIVE SPINAL SURGERY	2051556/R	ISD-A10TT00014	EVO – AXIAL SPACER H14 with locking pin
K0103 - DEVICES FOR MINI-INVASIVE SPINAL SURGERY	2051557/R	ISD-A10TT00016	EVO – AXIAL SPACER H16 with locking pin
K0103 - DEVICES FOR MINI-INVASIVE SPINAL SURGERY	2014847	ISD-B00T500000	EVO - Locking Pin
K0103 - DEVICES FOR MINI-INVASIVE SPINAL SURGERY	2051558/R	ISD-B10T500000	EVO - Long Locking Pin