

ALAYA SPINE SURGICAL INSTRUMENTS – DATA SHEET

General Description

ALAYA Surgical Instrument Kit is intended to be used with the ALAYA Spine Robotic Assistant as surgical instruments to assist during spine surgery for invasive and non-invasive steps of the clinical procedures.

They provide a precise robotic surgical solution for people with spinal pathologies (vertebral fractures, spinal stenosis and kyphosis, among others) requiring transpedicular screw insertion surgery.

Regulatory Compliance

The product meets safety and performance requirements of MDR (EU) 2017/745 for Class IIa and Class I Reusable medical devices.

Special MDR characteristics

The product is a procedure pack. Some of the surgical instruments provided in the container, and the container itself, have already been certified and have their corresponding CE mark.

Technical Details

Container size: 300 x 470 x 160 mm

Cleaning and disinfection method: manual and automatic, as defined in the IFU.

Sterilization method: Steam pre-vacuum cycle, as defined in the IFU.

Content and quantity

Number	Element	QTY	Manufacturer
0	Container	1	KLS Martin Group
1	K-wire adapter	2	Cyber Surgery S.L.
2	Drill bit	2	Hipp Medical AG
3	Awl	1	Cyber Surgery S.L.
4	Small bone clamp	2	Cyber Surgery S.L.
5	Medium bone clamp	2	Cyber Surgery S.L.
6	Large bone clamp	1	Cyber Surgery S.L.
7	Tester tool	1	Cyber Surgery S.L.
8	Screwdriver	1	Hermann Medizintechnik
9	AB Tool Guide	1	Cyber Surgery S.L.
9	Hammer	1	KLS Martin Group
10	Dilator	1	Cyber Surgery S.L.
11	Drill guide	1	Cyber Surgery S.L.
12	Large bone clamp	1	Cyber Surgery S.L.
13	Medium bone clamp	2	Cyber Surgery S.L.
14	Small bone clamp	2	Cyber Surgery S.L.

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