Clinical Study on the Safety and Efficacy of the Minimally Invasive Ennovate® Method for Pedicle Screw Placement

NCT06960018

Status	RECRUITING
Phase	Not Applicable
Sponsor	Aesculap AG
Enrollment	76 participants

Key Eligibility Criteria

Inclusion (1)

- All patients with minimum 18 years of age receiving Ennovate® Cervical internal fixation device within the vertebral bodies C2-Th3 to ensure the restoration and stabilization of the cervical spine

Exclusion (7)

- All patients not willing to sign the patient consent are excluded. Also, if it is clear from the beginning, that the patient will not be able to come to routine follow-up, the patient will also be excluded.
- Absolute contraindications according to the IFU:
- Severe damage to the bone structures of the spine that could prevent the stable implantation of the implant components; for example, osteopenia, severe osteoporosis, Paget's disease, bone tumors etc.
- Metabolic or degenerative metabolic bone diseases that could compromise the stable anchoring of the implant system.
- Suspected allergy or sensitivity to the implant materials.

... and 2 more (see full listing online)

Locations (3 total)

Universitätsklinikum Aachen, Aachen, Germany
Charité Berlin, Berlin, Germany
Universitätsklinikum Freiburg, Freiburg im Breisgau, Germany