ON REGISTER

SC MEDICA

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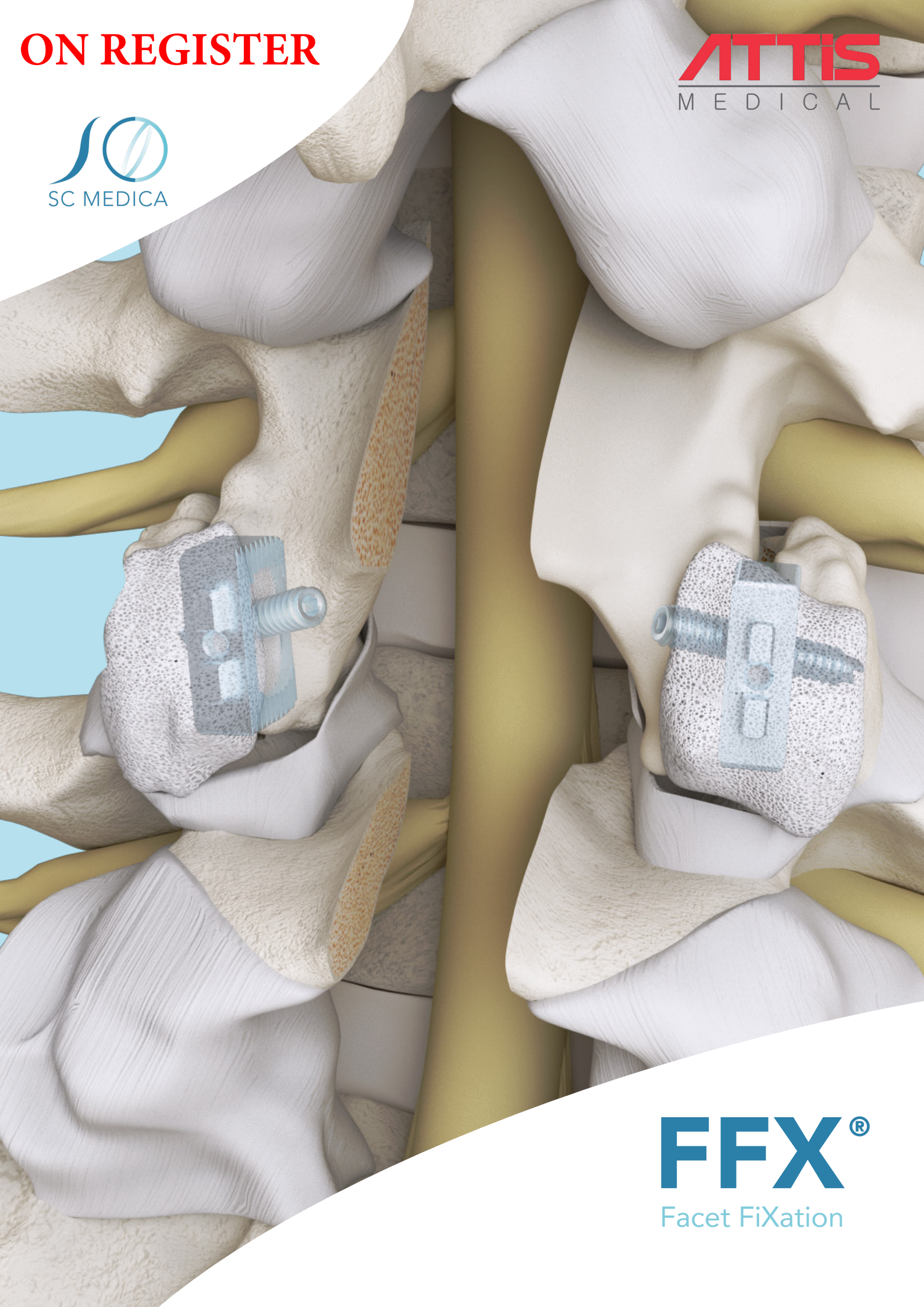


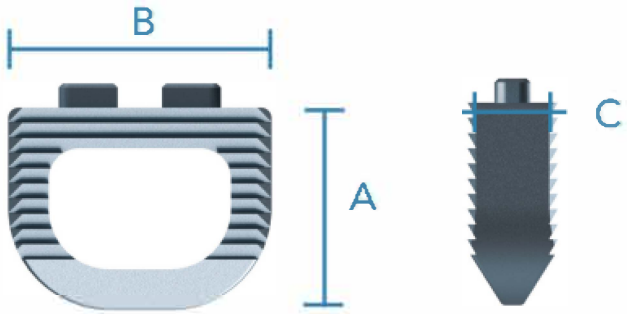
FFX®

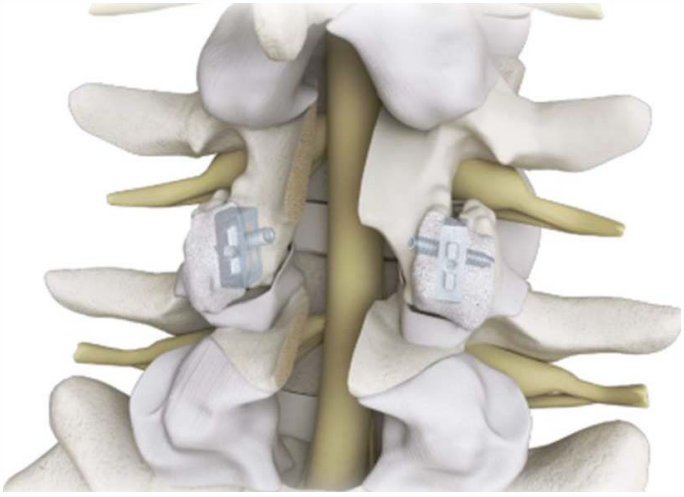
Facet FiXation

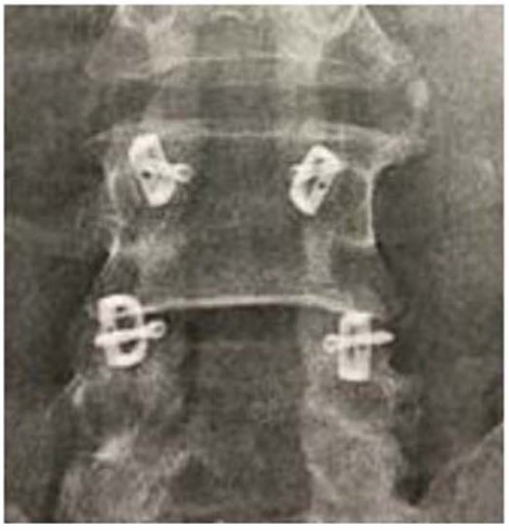
List of references

The choice of the size of the **FFX®** cage to use depends on the patient's anatomy.

Reference	A (mm)	B (mm)	C (mm)	Color
57.000.10S	10	11	2.5	Gold
57.000.20S	10	13	2.5	Dark blue
57.000.30S	10	11	3	Green
57.000.40S	10	13	3	Light blue
57.000.50S	10	11	3.5	Brown
57.000.60S	10	13	3.5	Purple







Surgical indications, intended use:

SC Medica FFX is a lumbar facet device that is placed bilaterally through a posterior surgical approach and spans the facet interspace. SC Medica FFX must be used with an FDA-cleared transfacet screw cleared for use in the lumbar spine. SC Medica FFX is intended to provide temporary fixation and stabilization to the spine as an aid to lumbar fusion through bilateral immobilization of the facet joints at one or two levels with autogenous and/or allogenic bone graft. SC Medica FFX must be accompanied with an FDA-cleared intervertebral body fusion device and/or with an FDA-cleared posterior lumbar pedicle screw and rod system implanted at the same spinal level(s) as an adjunct to a single or two-level intervertebral body or posterolateral fusion, respectively. SC Medica FFX is indicated for the treatment of patients with lumbar degenerative disc disease (DDD) from L3 to S1 in skeletally mature patients who have failed conservative care.

The use of FFX® cages is contraindicated in the following situations:

- Severe or chronic infections, local or systemic
- Allergy to titanium
- Bone destruction or demineralization potentially affecting the fixation of the cage
- Severe muscular, neurological, or vascular deficiencies affecting the limb in question
- Any infection that could compromise the function of the cage
- Active or prior infection at the surgical site
- Morbid obesity of the patient (e.g., BMI > 40)
- Psychiatric background
- Osteoporosis (T score of -2.5 or lower)
- Major spine instability (spondylolisthesis ≥ grade II)
- Fracture of the spine, isthmic lysis
- Scoliotic deformities (Cobb Angle >25°)
- More than 3 vertebral levels requiring surgical treatment
- Non-contiguous lumbar levels requiring surgical treatment
- Spondylodiscitis or spine tumor
- Wide resection of facet joints during the surgery or other type of decompression requiring more bone removal than a laminectomy
- Unilateral application of the device

FFX ST EN1 - REV 00 (For the US market only)

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