

K955710

SUMMARY OF SAFETY AND EFFECTIVENESS

Regulatory authority : Safe Medical Devices Act of 1990, 21 CFR 807.92

Company : J.B.S
Parc d'activités Savipol
10000 Ste Savine, Troyes
Tel : 011-33-2571-2500
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Medical Device
Establishment Registration # : 9681258

FDA Owner/Operator # : 9021265

Contact : Mrs Liza Burns, Regulatory consultant.

Trade name : J.B.S T.T.A screw.

Common name : T.T.A screw.

Classification : Bone, fixation, screw.

Classification Code : 87 KWC.

Device description :
This is a single-use, permanent internal device.
This is a Flat-headed, partially threaded screw, designed to be used without any washer.
This screw is available in six sizes : (40, 45, 50, 55 and 60 mm).
This screw is made of surgical implant Titanium, Ti6Al4EVELI, according to ASTM-136-92 or to ISO 5832-3-90.

Indications or use :
Transposition of Anterior Tibial Tuberosity. Possibility of compression without adding any washer.

Contraindications :
The J.B.S T.T.A is not to be used for patients with active localized or systemic infection, patients who are pregnant or patients who have disease or other medical condition which inhibits the potential of bony fusion. (i.e., osteoporosis, kidney analysis, etc.).

Substantially equivalent devices :
1-The partially threaded bone screw manufactured by Howmedica, Inc.
2-The partially threaded bone screw manufactured by Synthes.

Distributed by J.B.S USA
204E Blithedale Avenue
Mill Valley
CA 94941

Made in France by
J.B.S
Parc d'activités Savipol
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