



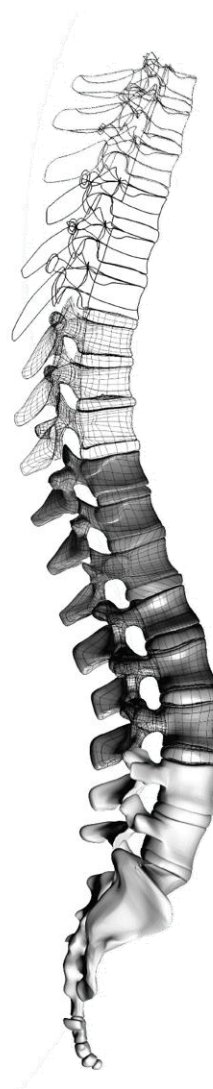
SPINOLOGICS

Leading the development of improved spinal care™

SCOLIOSCREEN

Indications For Use (IFU)

2018-03-07



CONCEPT

DESIGN

PRACTICE

DESIGN TEAM AND FOUNDERS

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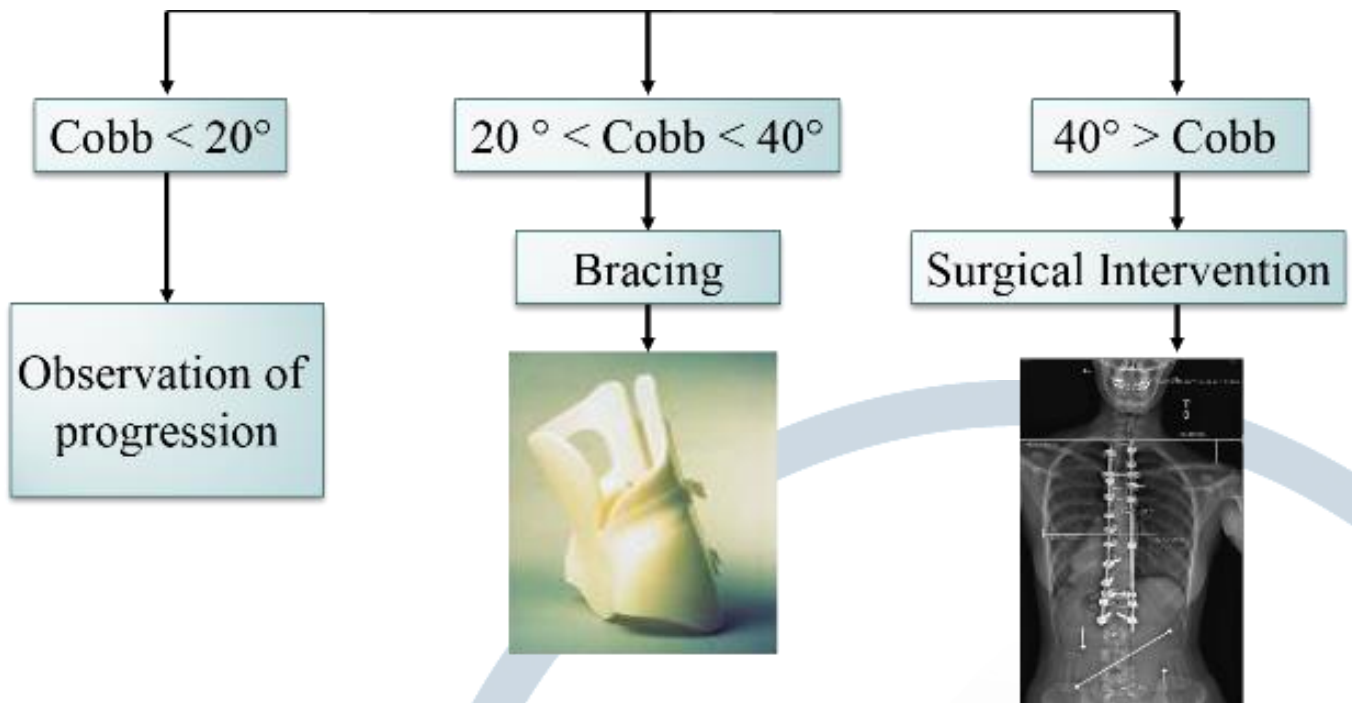
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INTRODUCTION

Scoliosis is a spinal deformity which affects about 4% of the population. The scoliotic treatment plan, shown below, is a progressive one because of the possibility of the spinal deformity getting worse. The advised treatment varies according to the magnitude of the Cobb angle which is measured from a coronal radiograph of the spine.

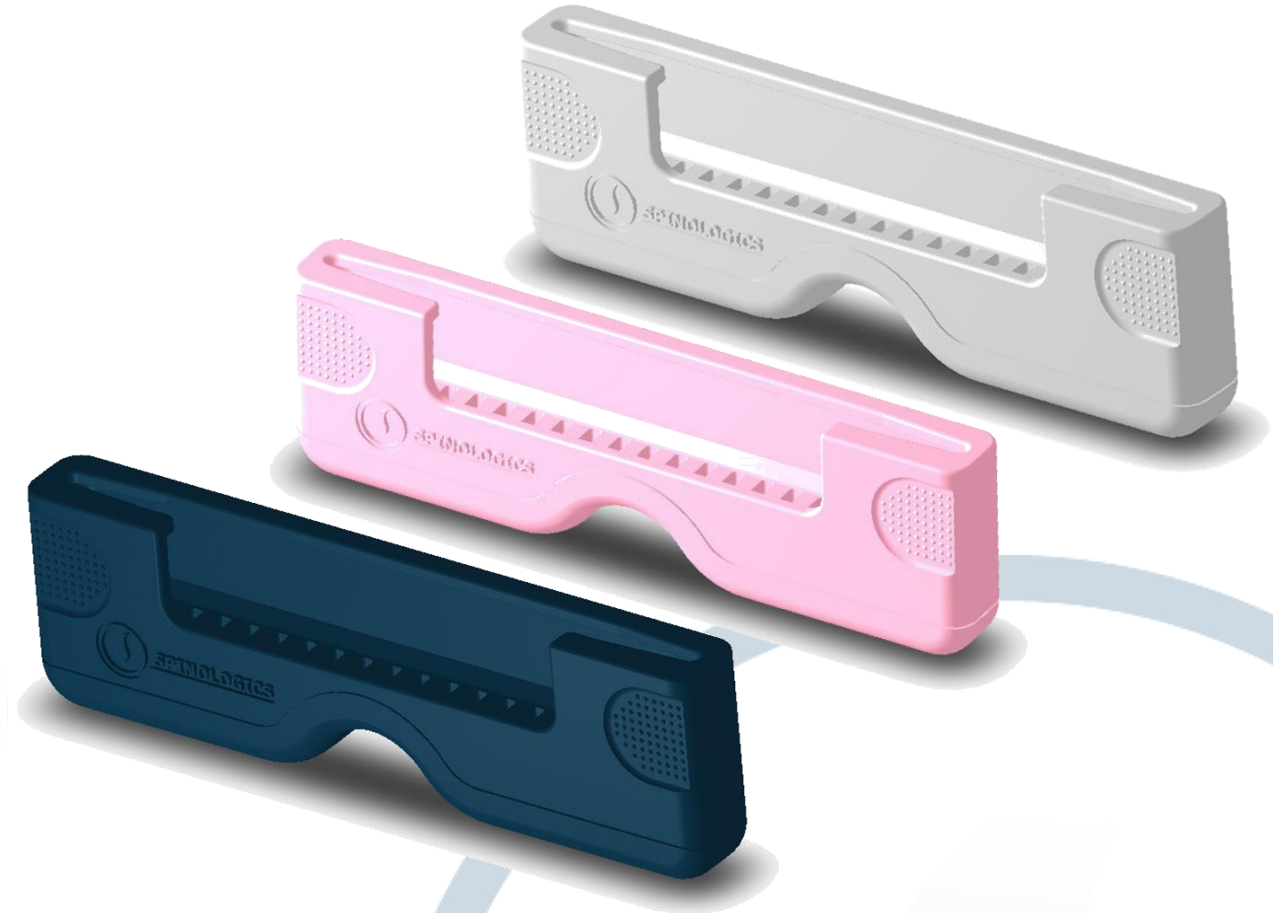


Early detection methods or screening programs that identify patients with scoliosis undoubtedly promotes and facilitates early intervention. Furthermore, these early interventions may deter the deformity from progressing to the point of requiring surgical interventions.

Scoliosis screening is achieved by measuring the angle of trunk rotation (ATR) which is correlated with the severity of spinal deformity. Having a patient bend forward, while the observer stands behind, exposes the angle of maximum deformity via the presence of a rib hump. This is the measure used to gauge the severity of one's spinal deformity.

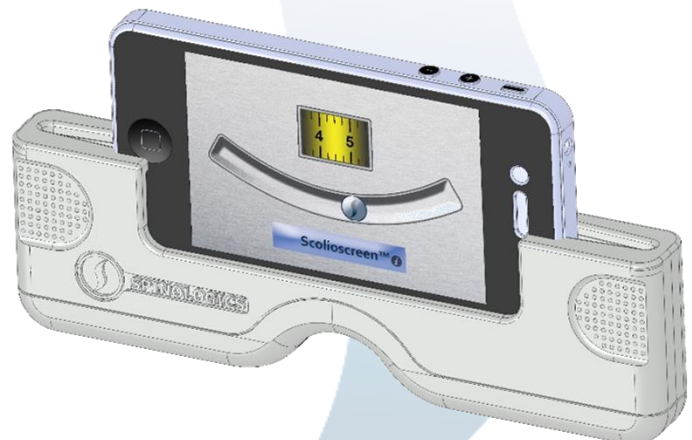


The Scolioscreen is a tool that allows for all smartphones, with or without a protective case, to be used to screen for spinal deformities. The Scolioscreen is made from a durable material and has a specially adapted base which is designed to conform to one's back - which is an important aspect to achieving an accurate measurement.



The Scolioscreen is a device that will work with all smartphones and all APPs measuring inclination angles with respect to the horizontal plane.

The Scolioscreen APP, available on iTunes, was specifically developed to allow the user to measure one's angle of trunk rotation.

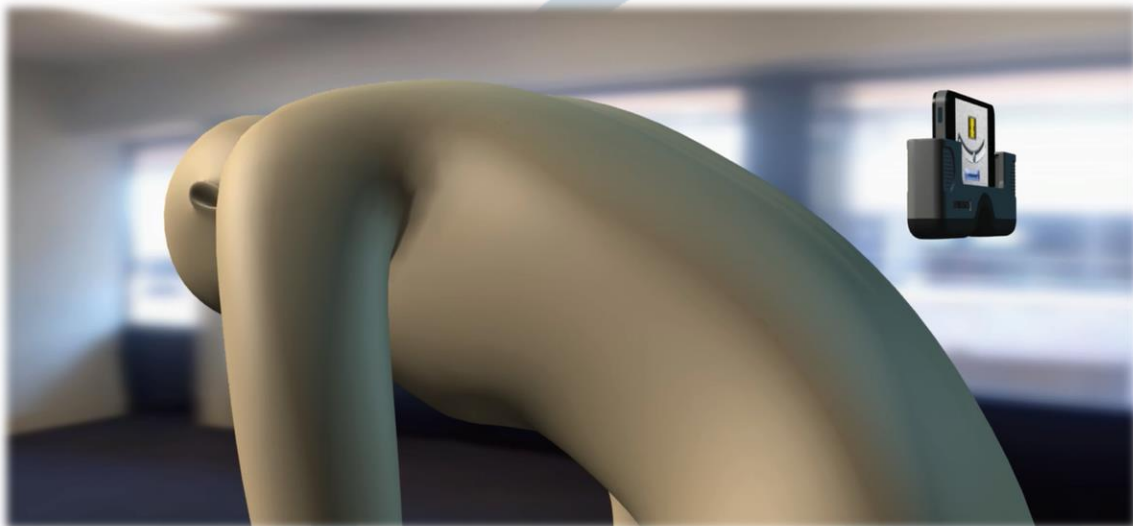


INSTRUCTIONS

- STEP 1. Start level APP and place smartphone in the Scolioscreen sleeve



- STEP 2. Have patient bend forward



INSTRUCTIONS

STEP 3. Position spinal process (spine bump) in the recess of Scolioscreen sleeve



STEP 4. Move Scolioscreen sleeve across spine



INSTRUCTIONS

STEP 5. Make note of maximum angle and review proposed guidelines



Scolioscreen™

Product number: SLS-500K

Indication for use: The Scolioscreen™ is designed to estimate spinal deformity severity by measuring the angle of truck rotation.

General: The Scolioscreen™ is a simple and convenient apparatus to screen and measure spinal deformities.

Storage: Store at room temperature.

Contraindications: None known.

CAUTIONS: The Scolioscreen™ does not replace the diagnosis of a medical physician as it serves as a facilitated spinal deformity screening.
Read enclosed instruction before use.

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