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3Shape Ortho System™ 2015 for orthodontics receives FDA 510(k) market clearance

Copenhagen, April 30, 2016 – 3Shape announces that the U.S. Food and Drug Administration (FDA) grants (510k) USA market clearance for its Ortho System™ 2015 software for orthodontics.

Ortho System enables orthodontic professionals to overlay DICOM, cephalometric, and 2D pictures along with intraoral scans for orthodontic case analysis and planning, treatment simulations and the design of FDA-cleared orthodontic appliances.

Professionals can use the software coupled with 3Shape lab scanners to create digital study models. Digital study models provide a space and cost saving alternative to traditional analog gypsum models.

Because Ortho System enables professionals to work digitally, they are able to share treatment planning and simulations onscreen with patients as well as seamlessly collaborate between clinic, lab, and 3rd party orthodontic solution providers via the 3Shape Communicate cloud platform.

This FDA market clearance includes 3Shape's new and innovative Indirect Bonding placement and transfer media solution, as well as several appliance design workflows that guide the user through the design phase and relevant production parameter settings.

Indirect bonding

The Ortho System indirect bonding application enables the accurate placement of vestibular brackets on the patient's malocclusion with the help of real-time collision detection tools. In addition, it allows the manufacturing of transfer media using a wide range of cleared machines and materials. Labs can choose from previous generation to the latest edition 3D printers that are capable of directly printing transfer trays.

Appliance design

For appliance design, Ortho System features a step-by-step intuitive workflow for guiding users. The software automatically sets production parameters based on the type of production equipment and materials chosen for a given appliance. In the future, 3Shape will continue to add new appliance type workflows, production equipment, and materials. When available and cleared, these may be downloaded from the 3shape Download Center.

"3Shape constantly strives to provide more value for our customers. The FDA clearance for Ortho System™ now enables USA orthodontic practice and lab owners to take advantage of the most versatile and easy-to-use orthodontic solution on the market," says Allan Hyldal, Vice President of 3Shape Orthodontics

For orthodontic practices wanting to learn more about 3Shape Ortho System™, please go to, <http://www.3shape.com/discover/orthodontist>

For orthodontic labs wanting to learn more about 3Shape Ortho System™, please go to, <http://www.3shape.com/discover/orthodontic+lab>

About 3Shape

3Shape creates 3D scanning and CAD/CAM software solutions. Award-winning technology that enables dental and hearing professionals to treat more people, more effectively and with improved care. A privately-owned company, 3Shape has over 700 employees with a product-development force of more than 275 professionals. Offices and service centers located in the Americas, Asia and Europe serve customers in more than 100 countries. Company headquarters are in Copenhagen, Denmark. www.3shape.com

