SureSmile® Clear Aligners

A proven system to predictably treat malocclusion

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Executive summary

Malocclusion is a pervasive oral health issue associated with numerous diseases and conditions that may affect a patient's overall health and quality of life. Guided by decades of orthodontic expertise, SureSmile® offers the technical support, clear aligner options, and proprietary planning methods to help clinicians address malocclusion with customized and predictable treatment plans for their patients.

The impact of malocclusion does not stop at the oral cavity.

Oral health issues associated with malocclusion are themselves linked to a range of systemic health problems.

Bacteria from the oral cavity have been identified in Alzheimer's lesions¹ and in atherosclerotic plaques², and periodontal disease is a well-documented risk factor for cardiovascular disorders³, stroke⁴, and impaired glucose control⁵.

There is also evidence that the systemic spread of oral bacteria may induce chronic systemic inflammation. As patients with severe malocclusion often have difficulty chewing their food, some researchers have suggested a link between malocclusion and gastrointestinal disorders such as acid reflux and leaky gut syndrome⁶.

Additional research is beginning to uncover how underdeveloped jaws and malocclusion may contribute to upper airway resistance and obstructive sleep apnea⁷.

Beyond the physical pain and discomfort associated with misalianed teeth. the esthetic impact of malocclusion can undermine patients' self-esteem, confidence, and social lives. Multiple studies have found that malocclusion negatively affects the psychological wellbeing of adults, many of whom experience anxiety, depression, and interpersonal difficulties as a result of concerns over their appearance8.

These findings underscore the importance of considering all aspects of a patients' oral health including their behavior, attitudes, and other risk factors—when assessing malocclusion and developing a treatment plan.

Malocclusion is a pervasive oral health issue associated with numerous diseases and conditions that may affect a patient's overall health and quality of life.

SureSmile® Clear Aligners: A discreet treatment modality that addresses form and function

Clear aligners play an important role in the treatment of malocclusion. In the hands of a doctor, aligners can do more than improve esthetics by aligning the "social six" teeth patients associate with their smile. Clear aligners can effectively treat the entire mouth, correcting a broad array of malocclusions and potentially alleviating associated oral health issues to improve the patient's health in a holistic fashion.

Clear aligner therapy also addresses a common patient concern about undergoing orthodontic treatment by allowing them to predictably achieve their desired outcome without the use of unsightly and uncomfortable brackets and wires.

Backed by Dentsply Sirona—a global leader in dental solutions with over one hundred years of experience in oral healthcare— SureSmile Clear Aligners correct malocclusion in a deliberate, strategic, and holistic fashion. Expert technicians in the SureSmile® Digital Lab build customized setups and staging for clear aligners by applying more than 20 years of experience in orthodontic treatment planning to ensure doctors and their patients have an excellent treatment experience.

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Over two decades of pioneering digital orthodontics

1999 2008 2013 2020 2023 OraMetrix® Multi-piece SureSmile®U site SureSmile® SureSmile® launched surgical and published; cloud-Software Simulator globally restorative delivered CAD enhancements (powered by DS simulation system released released Core) introduced application to provide launched; CBCT chairside 3D-smile integrated with visualization to SureSmile® educate patients Software about their possible new smile and length of treatment 2009 1994 2004 2018 SureSmile® Orthodontic Workflow Academy Dentsply CAD system for CAD/CAM system automation of Digital Sirona acquires integrated with orthodontics Orthodontics SureSmile® introduced; SureSmile® VPro™ highlaunched; 1st combined founded; SureSmile® robotic wire Software; lingual & labial frequency production 3D scanner, cases planned System acquired vibration device with SureSmile® begun computer design by Dentsply Sirona; SureSmile® Software & multi-axis robots launched; Aligner FDA SureSmile® 510K marketing Software clearance commercial launch

The SureSmile® difference

Effective and predictable SureSmile treatment plans start with a high-quality digital impression. SureSmile® is an open platform that accepts digital impressions from Primescan® and other commonly used intraoral scanners for

seamless integration into existing

digital workflows.

Diagnosis

Intraoral scans, X-rays, smile photos, and CBCT images are combined by experienced technicians using advanced software tools to build complete 3D models of the crowns and gums, including roots and bone.

In a study published in the American Journal of Orthodontics & Dentofacial Orthopedics, SureSmile software's 3D models provided the best combination of accuracy, reproducibility, and time efficiency of measurement⁹.

After the quality of each 3D model has been verified by SureSmile's Data Integrity team, intraoral and extraoral photos are used to establish the global position of the model, which is the natural position of the smile on the patient's face. Setting the correct global position of the model using all records provided by the clinician ensures that treatment planning begins how the patient presents.

Effective and predictable
SureSmile® treatment plans start with a high-quality digital impression.



SureSmile® planning software suggests the most efficient treatment path.



With an established link between patient records and 3D models, SureSmile Digital Lab technicians can begin digitally aligning the teeth according to the doctor's prescription. Supported by proprietary treatment planning software and visualization tools, SureSmile Digital Lab technicians can reliably plot an efficient and predictable approach to correct malocclusion, while ensuring

forces are applied judiciously, and refinements are minimized. This expertise is the foundation of the partnership between clinicians and the SureSmile Digital Lab, resulting in treatment plans customized for each patient based on their specific needs and goals.

The final setup, or the model of the desired treatment outcome, is reviewed by the Quality Control team before each patient's treatment plan is divided into stages.

Staged models

Staging design involves several levels of quality assurance. As a tooth moves across any of the three planes of motion (sagittal, coronal, and transverse), a number of factors can interfere with a smooth, gradual, and predictable movement. How teeth move across the three dimensions of space can greatly influence the success of reaching the desired outcome. SureSmile incorporates the biomechanics of tooth movements, published research, experience from our founding orthodontists, and a digital lab with exceptional attention to detail to make you feel sure about the smiles we are creating. SureSmile digital lab technicians assess each plan to flag any movements that could be achieved more easily or should be avoided; this ensures that clinicians and their patients benefit from SureSmile's extensive orthodontic knowledge and experience. Furthermore, our proprietary software incorporates powerful artificial intelligence to

(a) Accommodation staging — enhancing patient compliance by easing into treatment

automate staging calculations.

SureSmile Digital Lab experts are always at the center of the planning process, applying logic and a concern for the patient's well-being to every case. This ensures that considerations like patient comfort are incorporated into the treatment plan.

For example, in many cases, SureSmile technicians recommend starting off with simple, comfortable movements to help encourage patients to stay compliant with treatment. We refer to this as "accommodation staging"— which pushes some of the more uncomfortable tooth movements until later in the treatment plan so patients can get used to wearing their aligners before more forceful movements are applied.

b Variable tooth movement constraints

Digital lab technicians use SureSmile software to calculate and customize the ideal amount and speed of tooth movement every patient needs for optimal outcomes. These movement rates, sometimes called "aligner constraints," are based on observations and proprietary calculations pioneered by our founding orthodontists. These constraints balance a number of factors to arrive at an individualized recommendation for treatment staging:

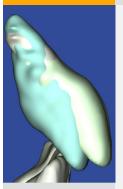
- Patient safety
- Average rates of biological tooth movement when subject to optimum mechanical force
- · How much movement is desired during each stage?
- · Which movements are combined into a single stage? Do they work with each other or against?

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Comparative Case Study: SureSmile® tooth movement system applied to an incisor

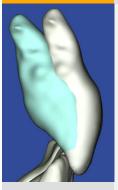
Case 1



Synergistic movement

- Clinician wishes to apply +8 degrees of torque and +0.8 mm of buccal movement with intrusion to an incisor.
- Facial crown torque and buccal movement are considered synergistic, they can be combined to improve the outcome.
- The rate of movement can be safely increased vs a scenario where facial torque and buccal movement are applied to the tooth in separate stages without sacrificing predictability.

Case 2



Antagonistic movement

- Clinician wishes to apply –8 degrees of torque and +0.8 mm of buccal movement to an incisor.
- Lingual crown torque and buccal movement are considered antagonistic, the conflict between them impedes the expression of either or both movements.
- The rate of movement should be reduced vs a scenario where lingual torque and buccal movement are applied to the tooth in separate stages to ensure both movements are fully expressed.
- To compensate for the slower movement rate, SureSmile software will identify other (standalone or synergistic) movements that can be safely accelerated so the net result is a steady, predictable treatment plan.

Key take-away: The SureSmile Digital Lab assesses all the forces being applied to each tooth throughout a clinician's proposed treatment plan. SureSmile then uses that information to recommend the most efficient and least disruptive set of movements needed at each stage of the plan for a successful, predictable outcome. Synergistic movements require less force and often involve more movement of the crown. Antagonistic movements require higher forces and are expressed over more aligners. When possible, we prefer to stage these combinations of movements independently.

Blue represents the tooth position before movement is applied. Green represents the tooth position after planned movements have been fully expressed.

d Attachments

To achieve the desired treatment outcome, some SureSmile treatment plans may include the use of attachments. SureSmile's treatment planning software automatically determines which attachment shape and location are necessary to achieve the desired movement for each tooth. Ellipsoid, rectangular, and beveled attachments can help aligners move the teeth whether rotation, angulation, extrusion, or intrusion are the goal. In all cases, the software suggests ways to optimize and minimize the number of attachments used to achieve predictable results to avoid refinements.

e SureSmile® trimlines: various selections to fit the diagnosis of your individual patient's needs

Trimlines are a powerful tool that give clinicians control over the amount of force applied to the teeth, independent of attachments—which is why SureSmile® offers 20 different trim heights and two trim lines (scalloped or straight)¹⁰. This wide range of options allows clinicians to select the appropriate trim based on clinical performance and patient factors.

SureSmile's straight trimlines follow a consistent height at or above the gingival zenith starting at 0 mm and increasing by increments of 0.1 mm up to 2 mm in height. Straight trimlines

have been shown to increase clear aligner stiffness and retention, and increase force to the tooth at the gingival third. This supports better force distribution and control of tooth movement¹⁰. Importantly, evidence on file indicates that stronger force systems often reduce the dependency on attachments¹⁰.

Considerations When Selecting a Trimline

Clinical & Patient Factors

- · Treatment goals, e.g.
 - Direction of tooth movement
 - Flexibility required for certain movement such as rotations or isolated extrusion
- · Amount of undercuts due to misaligned teeth and/or recession
- Tooth morphology
- · Severe recession
- · Spacing vs. Crowding
- · Tolerance to pain
- Compliance
- · Ability to remove/insert the aligners
- · Treatment goals, e.g.
- Treatment time
- Comfort during treatment
- Esthetics during treatment
- · Likelihood of compliance
- · Ease of removing and inserting aligners

Scalloped trimlines end at the iunction between the tooth crown and the gum tissue, so the aligner does not extend onto or above the gingival tissue. Scalloped trimlines may be considered a superior esthetic solution during aligner therapy. Given their relative flexibility, forces applied to the teeth near the gingival areas may be reduced¹⁰. In such instances, SureSmile can strategically apply attachments to reinforce the shape and tooth-moving effects of the aligner.

Application of Selected Trimlines

0 mm Straight Trim

· Suitable for most cases, balancing flexibility and stiffness

2 mm Straight Trim

- · Deep bite correction, leveling the curve of Spee
- Bodily movement
- Arch expansion
- Torque expression

Scalloped Trim

- Severe crowding
- · Isolated extrusion and rotations
- · Recession and large undercuts on tooth anatomy
- · Used when there is excessive spacing

Conclusion: The SureSmile-clinician partnership for beautiful smiles and better lives

Rooted in a deep understanding of orthodontic principles and propelled by state-of-the-art technologies, SureSmile empowers clinicians to treat the complexities of malocclusion with precision and compassion. From advanced software tools to seamless digital integration to high performance clear aligners, SureSmile is a trusted partner for doctors seeking to improve patients' oral health and well-being. Our system acknowledges the systemic implications of malocclusion, underscoring its impact on overall health and quality of life.

SureSmile empowers clinicians to treat the complexities of malocclusion with precision and compassion.

SureSmile Clear Aligners, backed by the extensive experience of Dentsply Sirona, offer a discreet and predictable modality to address both form and function. The carefully designed digital workflow ensures precision in diagnosis, treatment planning, and staged models, providing a customized approach tailored to individual patient needs.

The SureSmile difference lies in our meticulous attention to detail in treatment planning. By strategically addressing synergistic and antagonistic movements, the SureSmile Digital Lab optimizes tooth movement for a steady and predictable treatment outcome. The incorporation of attachments and the availability of diverse trimlines further empower clinicians to exert precise control

over force application, enhancing treatment efficacy and extending treatment to conditions that could not be treated with a one-size-fits-all approach.

SureSmile's commitment to patient well-being is evident in considerations for comfort, compliance, and esthetics—allowing for a nuanced approach based on clinical and patient-specific factors.

SureSmile offers clinicians a sophisticated tool to deliver tailored and predictable malocclusion treatments.

Our holistic approach, from diagnosis to treatment planning and execution, has ultimately benefitted the oral health and overall well-being of over 1 million patients worldwide¹¹.

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Notes	

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