# Advancing Precision Medicine in Head & Neck Cancer : Patient Specific Solutions for Cancer Therapy

kallisio

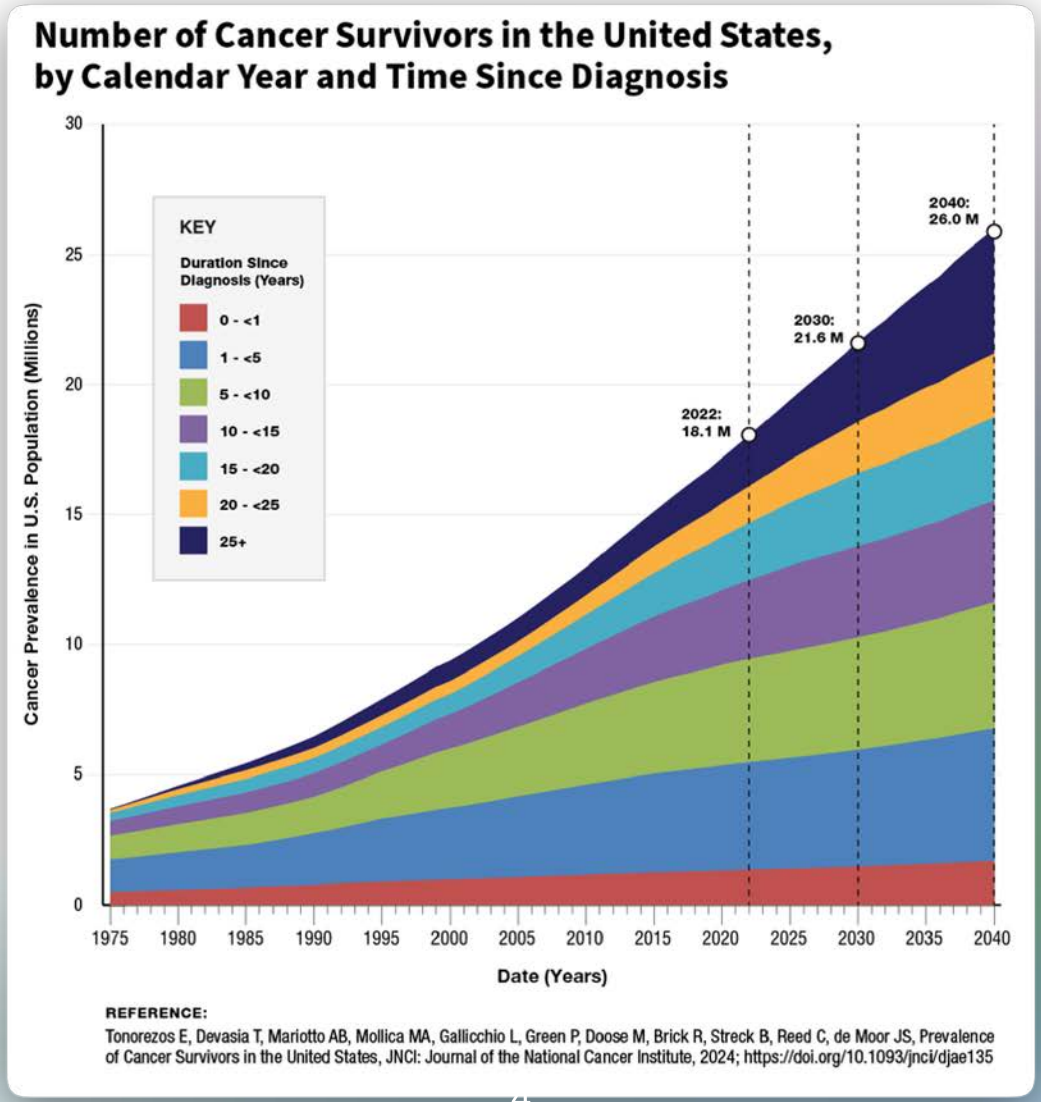
# Content

# A New Era in Cancer Care : Cancer A Chronic Condition

As cancer survivorship continues to rise, radiation oncology teams face a dual challenge: delivering curative treatment while preserving long-term function and quality of life. Nowhere is this balance more delicate than in head and neck cancer.

In these cases, toxicity is not just a side effect, it’s a limiting factor. Radiation-induced harm to oral structures can lead to long-term dysfunction in speech, swallowing, and nutrition. For today’s multidisciplinary care teams, preventing this harm is a clinical imperative, not a luxury.

Physicians, physicists, and therapists alike must align around a common goal: protect healthy tissue without compromising tumor control. This is the new standard in precision care.




source: https://cancerstatisticscenter.cancer.org/

# Treatment-Related Side Effects : A Barrier to Optimal Care

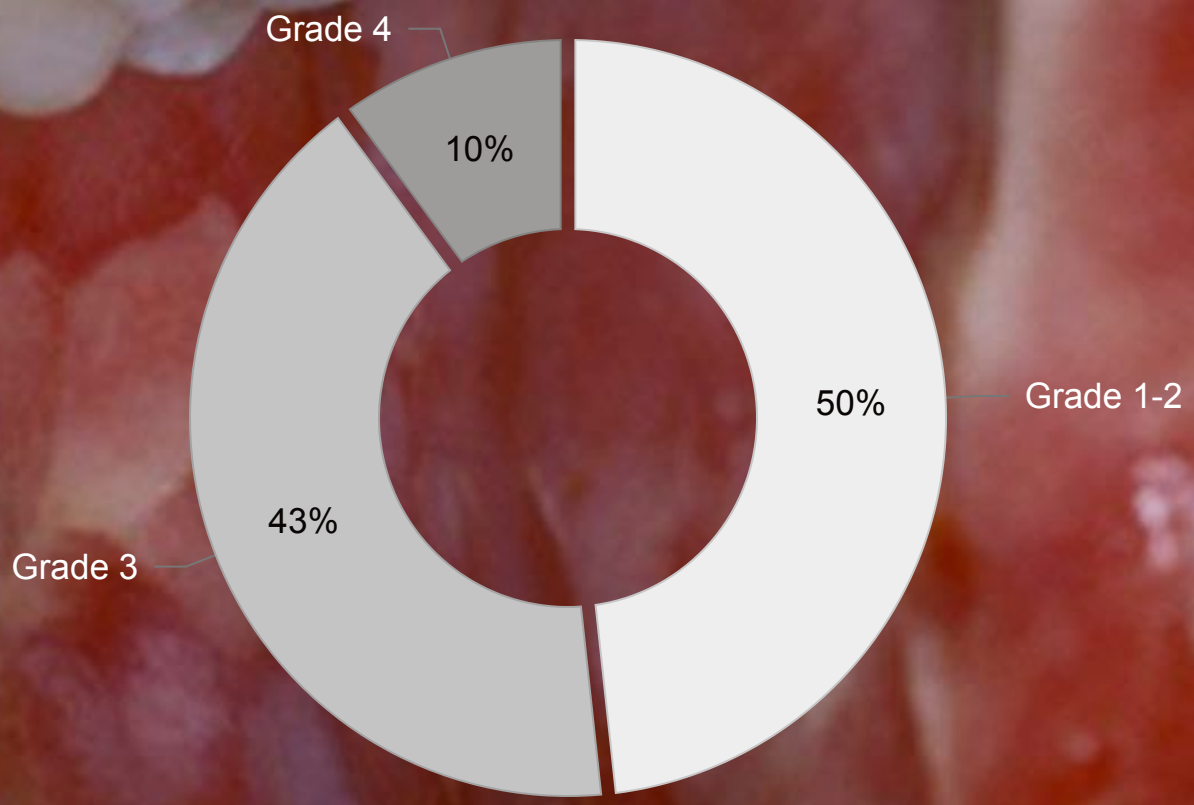
**Radiation is inherently non-selective, especially in anatomically dense regions like the oral cavity. Even with advanced planning techniques, suboptimal immobilization and tissue positioning can lead to unintended dose to non-target tissues.**

Standard tools such as bite blocks and tongue depressors fail to provide the precision required for reproducibility and anatomical displacement. Without better solutions, radiation teams are left navigating the balance between treatment efficacy and toxicity without sufficient control.

As professionals dedicated to precision, we must ask: how can we systematically reduce variability and improve protective outcomes across the care continuum?

# Oral Mucositis →

Radiation Induced Incidents by Grade




source: Elting LS, et al. *The burdens of cancer therapy: clinical and economic outcomes of chemotherapy-induced mucositis.* Cancer. 2008 Jan 1;113(10 Suppl):2706–13.

# The Cost of Inaction : Oral Mucositis and Its Ripple Effects

**Severe oral mucositis (OM) affects 34% to 43% of patients undergoing head and neck radiation. It is one of the primary causes of unplanned treatment breaks, enteral feeding, and hospitalization.**

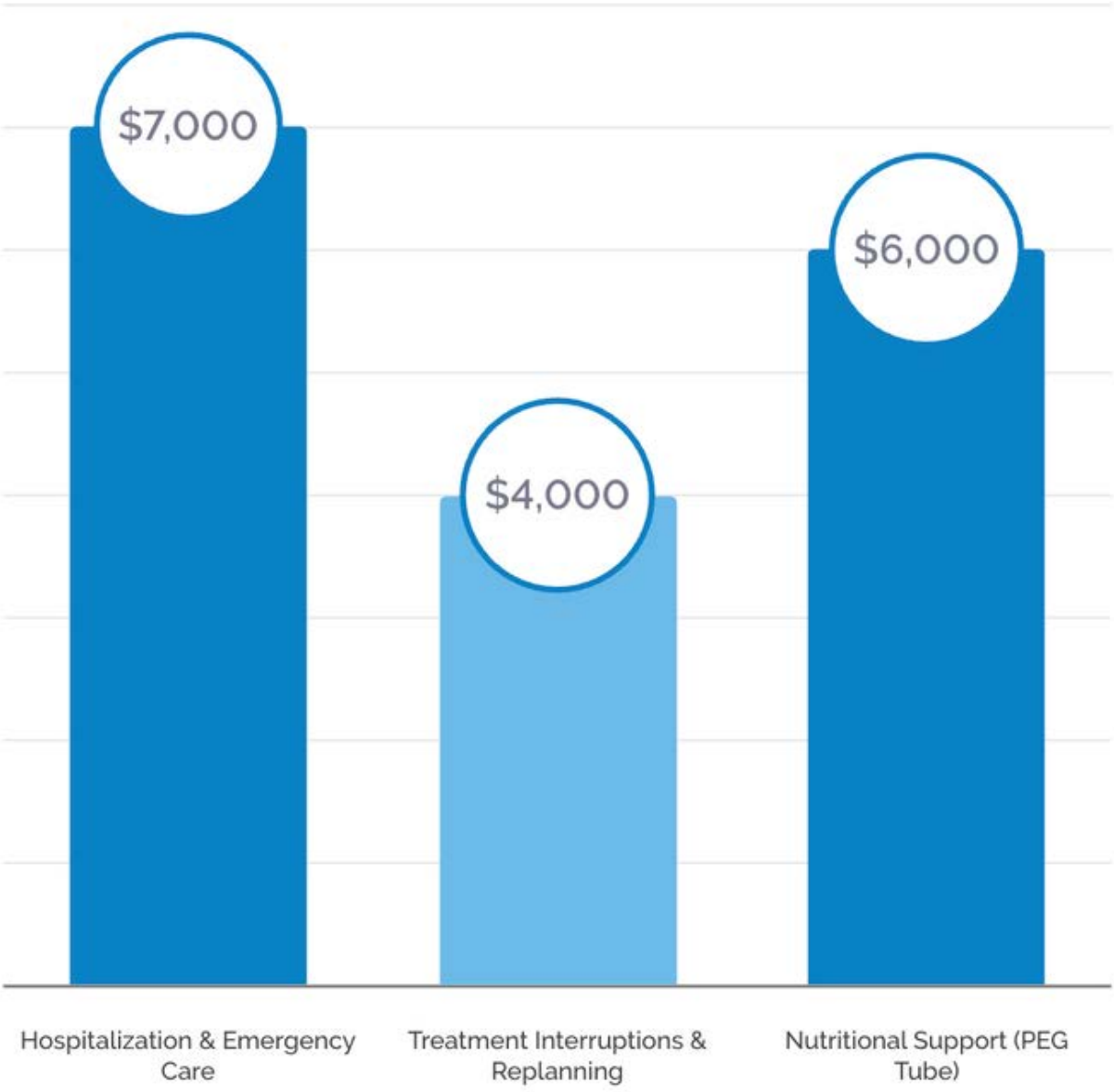
For clinical teams, OM means:

- ✓ Inconsistent dose delivery due to patient decompensation
- ✓ Treatment replanning and schedule delays
- ✓ PEG tube placements that can be avoided

For health systems, OM adds direct and indirect costs exceeding $17,000 per patient. But most importantly, it threatens the patient's experience and outcomes.

As radiation professionals, we have generic tools to prevent these complications. But we need solutions designed to meet a patient's unique anatomical requirements as well as the operational complexity of today’s clinics.

# Cost of Oral Mucositis



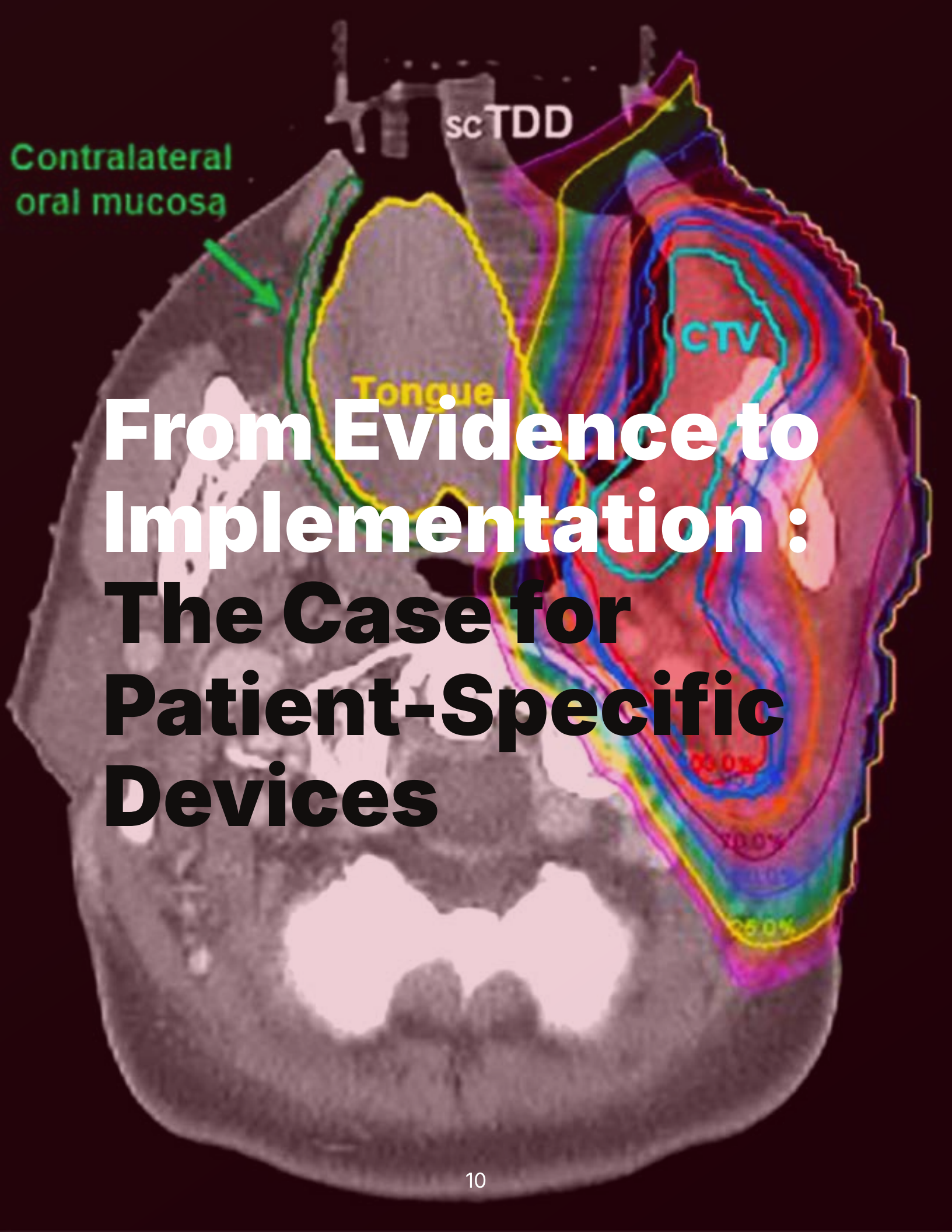

Source: Elting LS, Cooksley CD, Chambers MS, Garden AS. Risk, outcomes, and costs of radiation-induced oral mucositis among patients with head-and-neck malignancies.

# Cancer Advocacy Partners

Head & Neck Cancer Alliance

American Society For Radiation Oncologist

Support for People with Oral and Head and Neck Cancer




# From Evidence to Implementation : The Case for Patient-Specific Devices

# Peer-reviewed studies show that patient-specific intraoral devices can reduce rates of severe OM by up to 77.6%.

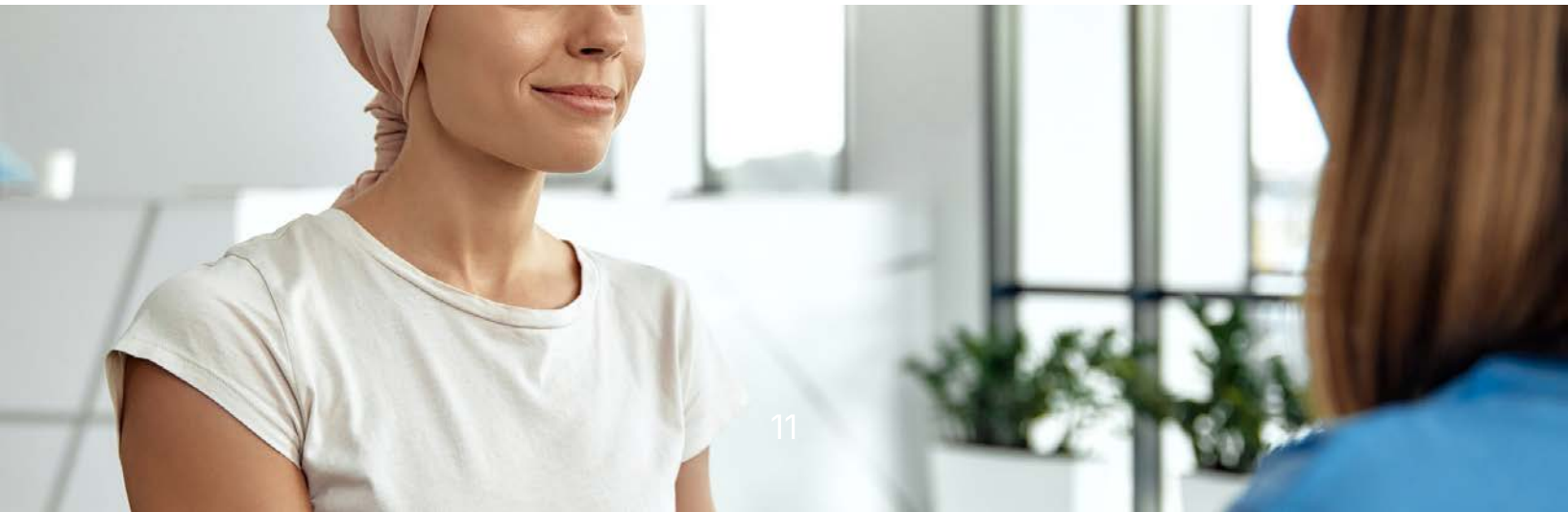
Custom oral stents are not a new concept, but modern technology has made them clinically viable at scale.

These devices:

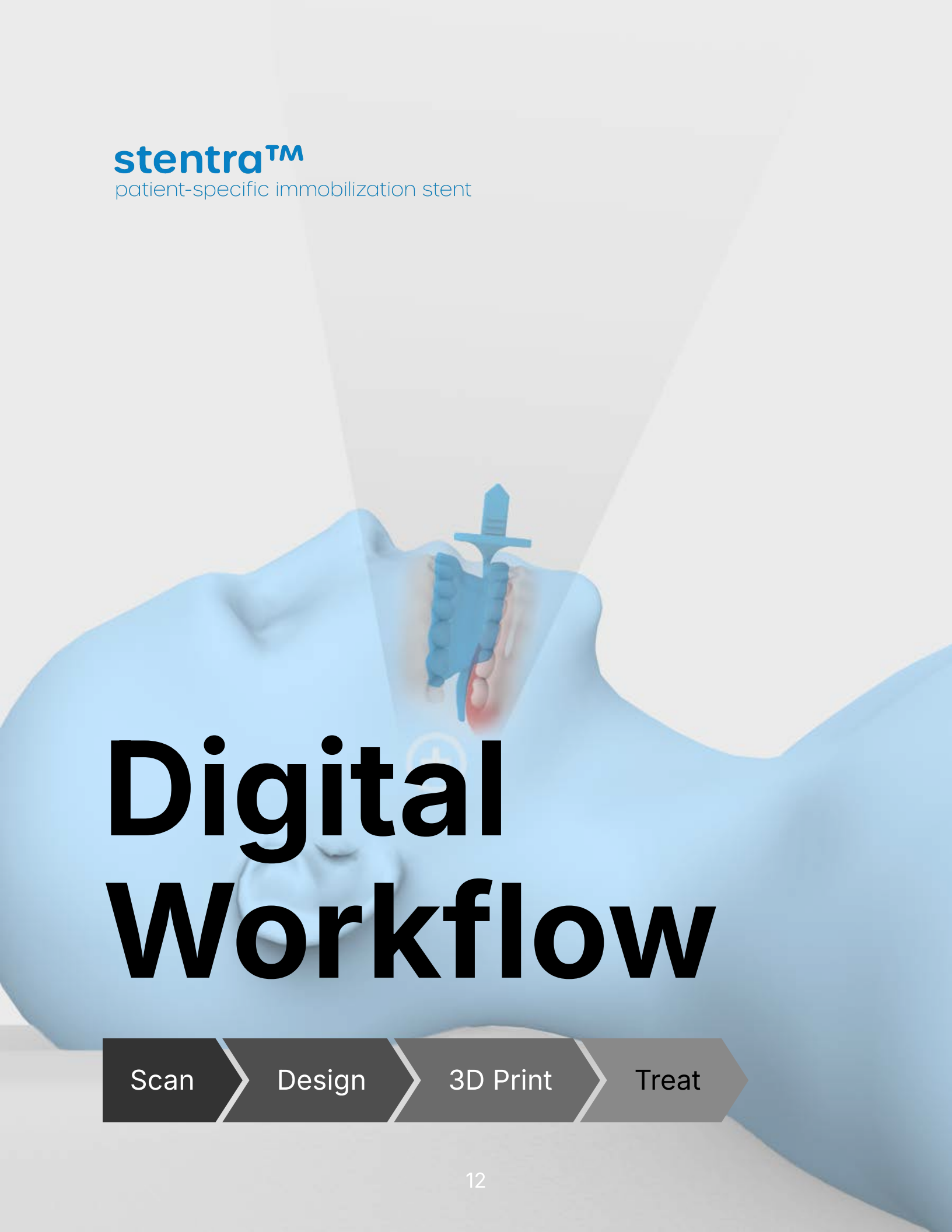
- ✓ Elevate and lateralize the tongue
- ✓ Displace sensitive tissues like the oral mucosa from the beam path
- ✓ Enable millimeter-level immobilization
- ✓ Improve reproducibility across treatment fractions

With digital scanning, CAD modeling, and 3D printing, a patient-specific workflow can now be implemented within 72 hours of simulation without requiring EHR integration.

O.M. Reduction source: Are Intraoral Stents Effective for Reducing the Severity of Oral Mucositis During Radiotherapy for Maxillary and Nasal Cavity Cancer? (Inoue, Y., Yamagata, K., Nakamura, M., Ohnishi, K., Tabuchi, K., & Bukawa, H. (2020)



stentra™
patient-specific immobilization stent



# Digital Workflow

Scan → Design → 3D Print → Treat

# stentra™ : A Clinical Workflow Tool for Modern Radiation Teams

**stentra™ is a patient-specific intraoral stent developed to integrate seamlessly into existing radiation workflows. Designed for oncologists, physicists, and therapists, it enhances anatomical control during treatment planning and delivery.**

**Key Benefits for Clinical Teams:**

- **Oncologists** gain peace of mind with reduced toxicity and fewer treatment breaks
- **Physicists** achieve greater dose conformity and OAR sparing
- **Radiation therapists** benefit from repeatable positioning and ease of setup

**Workflow Integration:**

1. Intraoral scan during consult or simulation
2. Upload via the Kallisio Clinical Portal
3. Receive 3D-printed device in 72 hours
4. Reusable throughout treatment, with included cleaning SOP

**Reimbursement:**

stentra™ is CPT-billable. No EHR integration required.

# Next Step: Invite Us Into Your Planning Room

Discover how stentra™ supports your radiation oncology workflow with precision, reproducibility, and patient-centered protection.

Book a 15-minute clinical consult or request a pilot kit: **email us at care@kallisio.com**

Because better tools mean better outcomes for your team and your patients.

# FAQs

### 1. Is Stentra™ reimbursable under existing CPT codes?

Yes. stentra™ is reimbursable under existing CPT codes used for custom radiation immobilization devices. Total reimbursement is dependant on the payer mix and documentation. We provide reimbursement guidance and documentation templates as part of onboarding.

### 2. What 3D printing process and materials are used to manufacture Stentra™?

stentra™ devices are fabricated using a biocompatible, medical-grade resin via high-resolution additive manufacturing process. This method ensures precision, repeatability, and a smooth surface finish optimized for intraoral comfort and fit.

### 3. How should the Stentra™ device be reprocessed between treatment sessions?

Each device is fully reusable throughout the treatment course. A validated reprocessing IFU and reusable container are included, allowing radiation therapists to reprocess and store the device between session using recommended instructions without compromising device integrity.

# FAQs (continued)

### 4. Is the Kallisio Clinical Portal HIPAA-compliant?

Yes. The Kallisio Clinical Portal is fully HIPAA-compliant. No Protected Health Information (PHI) is stored or transmitted through the system. Instead, cases are tracked using an auto-generated unique device identifier, ensuring patient privacy and institutional control.

### 5. Does the presence of the stent impact the radiation beam or planning accuracy?

No. stentra™ is designed using low-density, non-metallic materials that are fully visible on CT but do not attenuate the radiation beam. It integrates smoothly into existing planning workflows without requiring dose adjustments or beam compensation.

### 6. Why choose stentra™

It is the only FDA-cleared 100% patient-specific immobilization oral stent solution, with rapid turn-around-time of 72hrs, and customizable options to address unique patient tumor location. Available today!