UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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CLEARCORRECT OPERATING, LLC,
Petitioner,

v.

ALIGN TECHNOLOGY INC.,
Patent Owner.

---

Case IPR2025-00816
U.S. Patent No. 11,369,456

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**Declaration of Kelley M. Hayes Greenhill Regarding Ex-1016**

## I. Introduction

1. I have prepared this Declaration in connection with the above referenced *inter partes* review, which I understand will be filed concurrently with this Declaration.

2. I am currently the Director of the Research & Information Services team at Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, located at 901 New York Avenue NW, Washington, District of Columbia, 20001-4413 ("Finnegan").

3. I am over eighteen years of age, and I am competent to make this Declaration. I make this Declaration based on my own personal knowledge and my professional knowledge of library science practices.

4. I earned a Master of Science in Library Science from the Catholic University of America in 1995 and a Bachelor of Arts in Political Science from Duquesne University in 1989. I have worked as a librarian for over twenty-five years. I have been employed at Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, since 2019. Before that, from 1995 to 2015, I was employed in the Library Department of Sterne, Kessler, Goldstein & Fox, PLLC. And from 2015 to 2019, I was employed in the Knowledge and Research Service Group (formerly, Information Research Service) at Northrop Grumman Corporation.

5. I am a member of the American Association of Law Libraries.

## II. Standard Library Practices for Receiving, Searching, and Making Materials Publicly Available

6. I have knowledge of and experience with standard library practices regarding the receipt, cataloging, searching, accessing, and making print and electronic materials available to the public. I have knowledge of and experience with the Machine-Readable Cataloging (MARC) system, an industry-wide standard that libraries use to catalog materials. I also have knowledge of and experience with OCLC (previously called Online Computer Library Center, Inc.) and OCLC control numbers, which are unique accession numbers assigned by the OCLC system when a bibliographic record is cataloged and made available to the public through WorldCat. OCLC control numbers are often used by the public to search for specific records within WorldCat, which is an online database of 586,648,074 bibliographic records and 3,521,359,124 holdings from libraries throughout the world as of December 2024. Source: https://www.oclc.org/en/worldcat/inside-worldcat.html.

## III. Cataloging In Publication (CIP) Data

7. "CIP data" broadly refers to the bibliographic record created by the Library of Congress for a book before publication. Strictly speaking, however, "CIP data" is the bibliographic record that appears printed on the verso of the book's title page. It is an abbreviated version of the Machine-Readable Cataloging (or MARC) record that resides in the library's database and is distributed to libraries and book vendors. The full MARC version contains additional information, such as codes that

indicate the language in which the book is written and the date when the book was cataloged. The main purpose of a CIP record is to record the bibliographic data elements of a work and facilitate access to it in library catalogs.

8. For more information on the CIP data: https://www.loc.gov/programs/cataloging-in-publication/about-this-program/ (last visited Nov. 20, 2024).

## IV. MARC Records

9. The MARC record system was developed during the 1960s to standardize bibliographic catalog records so they could be read by computers and shared among libraries. By the mid-1970s, MARC had become the international standard for cataloging bibliographic materials and is still used today. Many libraries provide public access to their MARC records via the Internet and/or their electronic cataloging systems at the libraries. In a MARC record, each field provides specific information about the cataloged item, including how materials are held and when they were made available to the public.

10. The MARC record system uses specific three-digit numeric codes ("field tags") from 001-999 to identify each field in a catalog record. For example, field tag 008 provides the six-digit date the item was received and cataloged (date entered on file). The first six characters of field tag 008 are always in the "YYMMDD" format. Descriptions for all of the character positions of field tag 008

are outlined here on the Library of Congress website. *See 008 - All Materials (NR)*, The Library of Congress, https://www.loc.gov/marc/bibliographic/bd008a.html (last visited Nov. 6, 2024).

11. MARC field tags related to this Declaration are explained below. MARC field tag 020 provides the International Standard Book Number (ISBN), a unique identification number assigned to a monographic publication by designated agencies in each country participating in the program. MARC field tag 245 identifies the full title statement for the work, and field tag 260 identifies the place of publication, name of publisher, and copyright date of the publication. MARC field tag 992 details information required to locate and access local holdings.

## V. Monographs

12. A monograph is a comprehensive written study or scholarly work that focuses on a single subject or a specific aspect of a subject. It is a bibliographic resource that is complete in one volume or intended to be finished in a limited number of volumes. Typically, a monograph refers to a print publication of a single volume. Monographs differ from serial publications, such as magazines, journals, or yearbooks, which are published in installments.

## VI. International Standard Book Number (ISBN)

13. An ISBN serves as a unique identifier for a book, aiding its sale in both physical and digital bookstores as well as libraries. The term ISBN stands for

"International Standard Book Number." It is a numerical identifier rather than a bar code. Each country has a specific agency responsible for assigning ISBNs to publishers and self-publishers within its borders. In the United States, Bowker is the designated official source for ISBNs. Notably, the U.S. ISBN Agency cannot issue ISBNs to publishers and self-publishers located outside the United States and its territories.

14. The ISBN identifies the title or other book-like product (such as an audiobook) to which it is assigned, as well as the publisher to be contacted for ordering purposes. ISBNs are assigned to publishers and self-publishers in the following numbers: 1; 10; 100; 1,000; 10,000; or 100,000.

15. Publishers must report all title information for assigned ISBNs. ISBNs were originally 10 digits long but switched to a 13-digit format on January 1, 2007. If you have a 10-digit ISBN, you can convert it to a 13-digit format using a converter on a website. Conversion isn't simply adding three digits—an algorithm often alters the last digit. ISBNs help manage metadata and improve discoverability. Using an ISBN is the most accurate and reliable way to search for a book. Bowker has a search engine that can be used to find book information. The typical location of an ISBN is on the back cover of a book.

## VII. Internet Archive (Wayback Machine)

16. The Internet Archive is a website that provides access to a digital library

of Internet sites and other cultural artifacts in digital form. Like a physical library, it provides free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress, and is available here: https://archive.org/.

17. The Internet Archive has created a service known as the Wayback Machine (https://web.archive.org/). The Wayback Machine makes it possible to browse more than 450 billion webpages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address) or keyword. If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates and begin viewing an archived version of the webpage.

18. The archived data made viewable by the Wayback Machine is obtained by the use of web archiving software that automatically stores copies of files available via the Internet, each file preserved as it existed at a particular point in time.

19. The Internet Archive assigns a URL on its site to the archived files in the format: http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code inhh:mm:ss]/[Archived URL]. This is known as an "extended URL" format.

20. Thus, for example, the extended URL http://web.archive.org/web/19970126045828/http://www.archive.org/ denotes the URL for the record of the Internet Archive home page HTML file archived on January 26, 1997, at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28).

## VIII. Public Availability of *Tuncay*

21. This Declaration relates to the public availability of the following reference: Tuncay, Orhan C. *The Invisalign System*. London; Chicago: Quintessence, 2006 ("*Tuncay*"). I understand that *Tuncay* is being submitted as **Exhibit 1016** in this proceeding.

22. As detailed below, I have reviewed the print *Tuncay* reference which was supplied to me by Wisconsin TechSearch, a service of the University of Wisconsin, Madison; the National Library of Medicine catalog public holdings information; and the National Library of Medicine MARC record for *Tuncay*, to determine the date of public availability for this reference. I also reviewed information from the ISBN website and the Internet Archive, Wayback Machine.

23. **Appendix A** to this Declaration is a true and accurate copy of the cover page, title page, and table of contents for Tuncay, Orhan C. *The Invisalign System.* London; Chicago, Quintessence, 2006. **Appendix A** sets forth the unique International Standard Book Number (ISBN) for *Tuncay* as 1-85097-127-7; 978-1-85097-127-6.

24. **Appendix B** to this Declaration is a true and accurate copy of the National Library of Medicine public catalog record for its copy of *Tuncay*, which was downloaded from https://catalog.nlm.nih.gov/permalink/01NLM_INST/1o1phhn/alma9912853563406676 on November 14, 2024.

25. The National Library of Medicine public catalog record (**Appendix B**) sets forth the publication and holdings information for its copy of *Tuncay*. **Appendix B** also denotes that *Tuncay* bears the ISBN of 1850971277; ISBN: 9781850971276; and is "Available at NLM General Collection (2006 J-539)."

26. **Appendix C** to this Declaration is a true and accurate copy of the National Library of Medicine MARC record for its holdings of *Tuncay*, which was downloaded from https://catalog-utils.nlm.nih.gov/marc/bibs/nlmbib-9912853563406676/ on July 16, 2024.

27. **Appendix C** confirms the fixed data elements of MARC field tag 008 as 060320s2006 enka b 000 0 eng. As discussed above, the first six characters "060320" are in typical "YYMMDD" format and indicate that *Tuncay* was cataloged by the National Library of Medicine on March 20, 2006, and bears a publication single known year as 2006.

28. *Tuncay* appears to have been part of the CIP program based on the imprint on the verso page, denoting "British Library Cataloging in Publication Data"

(**Appendix A)**. As part of the Library Cataloging in Publication, the British Library created the bibliographic record for *Tuncay* prior to its publication. The general public had access to the bibliographic information for *Tuncay* before its print publication.

29. MARC record (**Appendix C**) field tag 020 sets forth the unique ISBN number belonging to *Tuncay* as __ | ‡**a** 9781850971276; __ ‡**a** 1850971277. MARC field tag 245 sets forth the title and statement of responsibility for *Tuncay* as 04 | ‡**a** The Invisalign System /‡**c** [edited by] Orhan C. Tuncay. MARC field tag 260 sets forth information relating to the place of publication, printing, distribution, and copyright date for *Tuncay* as __ | ‡**a** London ;‡**a** Chicago :‡**b** Quintessence,‡**c** 2006. Finally, MARC field tag 992 details information required to locate and access local holdings and denotes __ | ‡**p**P3‡**e**E4‡**a** 20060817, which indicates the date the print version of *Tuncay* was sent to cataloging.

30. On February 11, 2025, via email, I confirmed with the National Library of Medicine that its local rule for MARC tag 992 "provides coded information on the intended priority status and encoding level for the record and the date the piece is sent for cataloging." **Appendix I**.

31. Based on the information set forth in **Appendices A**, **B**, **C**, and **I** attached to this Declaration, standard library practices, and my experience as a librarian, *Tuncay* was cataloged by the National Library of Medicine on March 20,

2006, as a part of the Catalog In Publication program. The National Library of Medicine sent the print version of *Tuncay* to cataloging on August 17, 2006.

32. Accordingly, *Tuncay* would have subsequently been made available to the public within a few days of being cataloged. The interested public had access to *Tuncay* (i) by searching the National Library of Medicine catalog or (ii) by asking a Library staff member to direct them to the resource within a few days of August 17, 2006.

## IX. International Standard Book Number (ISBN)

33. The International Standard Book Number (ISBN) is a unique numerical identifier for books. It identifies the title and other book-like product (such as an audiobook) to which it is assigned and the publisher for ordering purposes. An ISBN is usually located on the back cover of a book. Using an ISBN is the most accurate and reliable way to search for a book.

34. On February 19, 2025, I used Google Chrome to navigate to the publicly available ISBN Search at the website https://isbnsearch.org/. I searched "1-85097-127-7," which resulted in webpage https://isbnsearch.org/isbn/1850971277 (**Appendix J**). This page displays the book title, *The Invisalign System*, and the author as "Orhan C Tuncay." This matches the information for *Tuncay* (**Appendix A**). This webpage further displays the publisher as "Quintessence Pub Co," which matches the publisher for *Tuncay* (**Appendix A**)

and indicates it was published "2006-08-01."

35. Based on the information in **Appendix J**, *Tuncay* would have been available on or after August 1, 2006.

## X. Internet Archive and Wayback Machine

36. On February 20, 2025, I used Google Chrome to navigate to the publicly available Internet Archive, Wayback Machine (https://web.archive.org/). I next entered "www.quintessencepublishing.co.uk" in the search bar, which resulted in the webpage https://web.archive.org/web/20250000000000*/www.quintessencepublishing.co.uk, which is appended here as **Appendix K**. From here, I clicked on "2006" in the timeline bar and clicked on July 17, 2006, which resulted in the webpage https://web.archive.org/web/20060717234203/http://www.quintessencepublishing.co.uk/, which is appended here as **Appendix L**. From here, I clicked "Click Here Enter," which resulted in the webpage https://web.archive.org/web/20060719005436/http://www.quintessencepublishing.co.uk/catalog/, which is appended here as **Appendix M**. From here, I clicked the icon for the book, *The Invisalign System*, which resulted in the webpage https://web.archive.org/web/20060721163138/http://www.quintessencepublishing.co.uk/catalog/product_info.php?products_id=280&osCsid=9dcff4bf0035f0bd7584c3d27ecb6eb5, which is appended here as **Appendix N**. There is a "Buy Now"

button on the bottom right of the page. Also, this page displays a date of "Friday, July 21, 2006" on the bottom left. The URL for this screen capture denotes "20060721163138," which indicates the file was archived on July 21, 2006, at 4:31 p.m. and 38 seconds (2006/07/21 at 04:31:38).

37. Based on the information set forth in **Appendices K**, **L**, **M**, and **N**, members of the interested public had access to purchasing *Tuncay* from the publisher's website in July 2006.

## XI. Conclusion

38. In signing this Declaration, I understand it will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I understand I may be subject to cross-examination in this case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

39. I declare that all statements made herein of my knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like

so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Executed on March 7, 2025, in the District of Columbia.

Kelley Hayes Greenhill

Kelley Hayes Greenhill

# Appendix A

# The Invisalign® System

Edited by
Orhan C. Tuncay, DMD

quintessence books

# The Invisalign System

Orhan C. Tuncay, DMD
Professor and Chairman
Department of Orthodontics
School of Dentistry
Temple University
Philadelphia, Pennsylvania

quintessence books

**Quintessence Publishing Co, Ltd**
London, Berlin, Chicago, Tokyo, Barcelona, Beijing,
Istanbul, Milan, Moscow, Mumbai, Paris,
Prague, São Paulo, and Warsaw

British Library Cataloging in Publication Data
1. Orthodontics, Corrective 2. Orthodontic appliances
3. Orthodontics – Diagnosis
I. Tuncay, Orhan C.
617.6'43'00284

ISBN-10: 1850971277

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ISBN-10: 1-85097-127-7
ISBN-13: 978-1-85097-127-6
Printed in Germany



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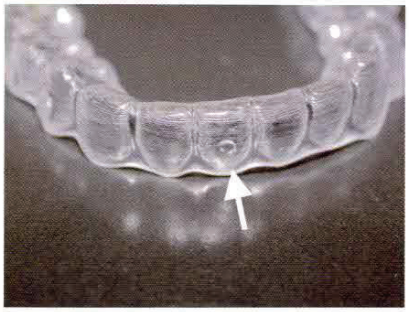

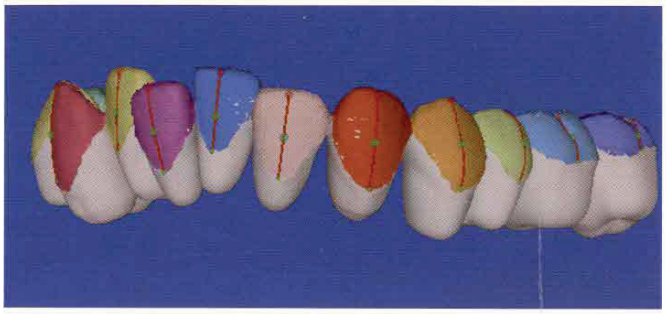


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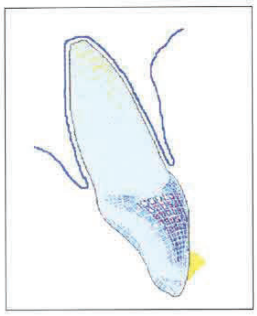

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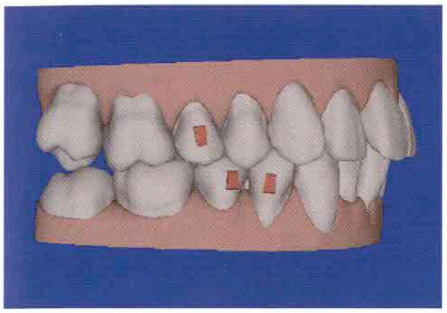
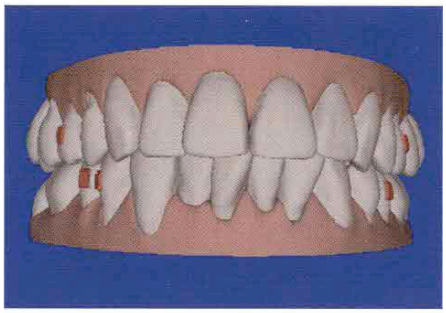
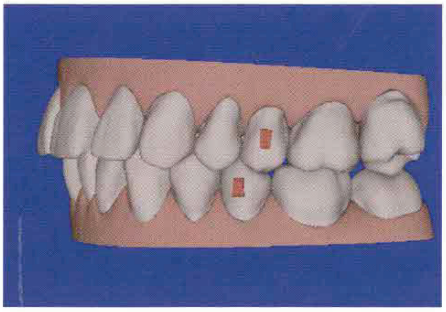


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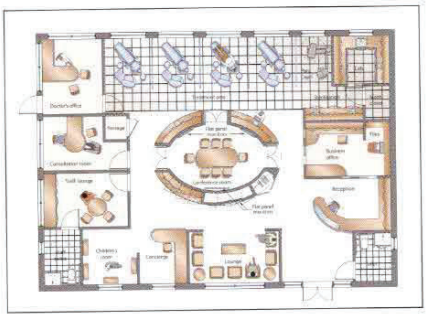

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# Preface

The long-awaited paradigm shift in orthodontics arrived with the introduction of the Invisalign System. This unique treatment approach has been instrumental in removing the ever-present shroud of mystery surrounding orthodontics by allowing both dental practitioner and patient to develop a visual understanding of orthodontic tooth movement. In this way, it has founded a culture of true and attainable visual treatment objectives. Moreover, the esthetic and practical advantages of the system have extended orthodontic services to a greater population.

The Invisalign System is multilingual. Its spoken languages are image acquisition, software (ClinCheck), and the Invisalign aligner. The dialects are the generation of forces, attachment designs, and response of periodontal tissues to the forces generated by the aligner. The regional accents were born through the various applications of ClinCheck, spectrum of cases treated, attachment preferences, and instructions to patients. The adoption of the Invisalign System into a practice, however, is a language unto itself. It has its roots in two different tongues: biology and technology. To be fluent in all of these languages and dialects, the clinician must know the root of the language and how the dialects have been derived.

This book, the first to be written about the Invisalign System, was compiled as an educational tool for all of the languages, dialects, and accents spoken in the world of Invisalign. It is not a how-to manual. Instead, it is designed to expose the clinician to behind-the-scene elements of customization that underlie the production of Invisalign aligners. Equipped with such information, the clinician will better understand the nature of tooth movement with the Invisalign System.

Our deepest gratitude goes to the authors from Align Technology. These individuals took precious time from their daily schedules to write about the inner workings of their operation. The Invisalign System is primarily company driven; therefore, it is their contribution that makes this textbook possible. In particular, Dr Trang Duong's indefatigability in collecting chapters from Align Technology authors is greatly appreciated. We gratefully acknowledge the monumental commitment of Align Technology, through the leadership of Amir Abolfathi, to this project. Finally, we thank Jonathan S. Simmons, whose efforts in the editing, organization, and overall preparation of the manuscript have been invaluable.

# Appendix B

BOOK

# The Invisalign System ; [edited by] Orhan C. Tuncay.

Tuncay, Orhan C.

London ; Chicago : Quintessence; c2006

Library Catalog ; MMS ID 9912853563406676; ISBN 9781850971276; ISBN 1850971277; NLM Unique ID 101285356

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## Details

| | |
|---|---|
| **Title(s)** | The Invisalign System<br>[edited by] Orhan C. Tuncay. |
| **Creator(s)** | Tuncay, Orhan C. > |
| **Publisher** | London ; Chicago : Quintessence<br>c2006 |
| **Country** | England |
| **Language** | English |
| **Description** | xiv, 320 p. : ill. |
| **Identifier(s)** | ISBN : 9781850971276<br>ISBN : 1850971277 |
| **MESH Subjects** | Orthodontics, Corrective ><br>Orthodontic Appliances ><br>Orthodontics > |
| **NLM Unique ID** | 101285356 |

# Appendix C

Skip to main content

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Menu

- MARC Download
- MMS ID Lookup

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- Download MARC21

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005 20211203233915.0
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042 __ | **‡a** pcc**‡a** nlmcopyc
044 __ | **‡9** England
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082 04 | **‡a** 617.64300284**‡2** 22
245 04 | **‡a** The Invisalign System /**‡c** [edited by] Orhan C. Tuncay.
260 __ | **‡a** London ;**‡a** Chicago :**‡b** Quintessence,**‡c** c2006.
300 __ | **‡a** xiv, 320 p. :**‡b** ill.
336 __ | **‡a** text**‡b** txt**‡2** rdacontent
337 __ | **‡a** unmediated**‡b** n**‡2** rdamedia
338 __ | **‡a** volume**‡b** nc**‡2** rdacarrier
504 __ | **‡a** Includes bibliographical references.
650 12 | **‡a** Orthodontics, Corrective
650 12 | **‡a** Orthodontic Appliances
650 22 | **‡a** Orthodontics
700 1_ | **‡a** Tuncay, Orhan C.
935 __ | **‡a** (DNLM)1285356-nlmdb
992 __ | **‡p** P3**‡e** E4**‡a** 20060817
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994 __ | **‡a** CDN**‡b** 20060918
995 __ | **‡a** AUTH**‡b** 20060927**‡c** REV**‡d** 20180131
999 __ | **‡a** AUTH

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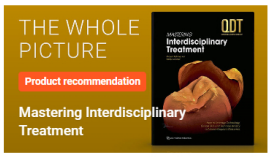

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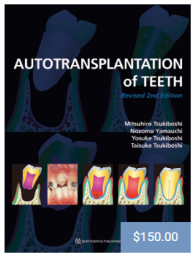
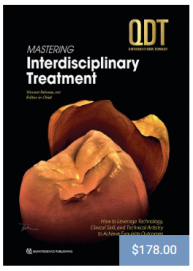



Mitsuhiro Tsukiboshi / Nozomu "Noz" Yamauchi / Yosuke Tsukiboshi / Taisuke Tsukiboshi

**Autotransplantation of Teeth**

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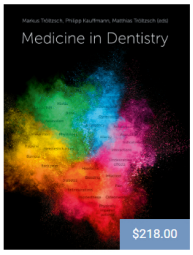
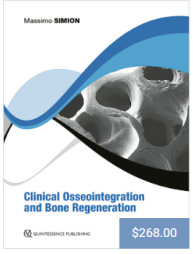
How to Leverage Technology, Clinical Skill, and Technical Artistry to Achieve Exquisite Outcomes




Markus Tröltzsch / Philipp Kauffmann / Matthias Tröltzsch (Editor)

**Medicine in Dentistry**




Massimo Simion

**Clinical Osseointegration and Bone Regeneration**

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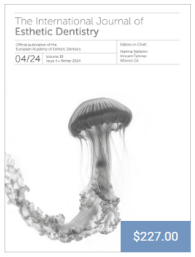


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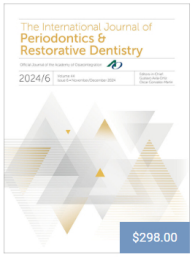
**International Journal of Oral Implantology**




**International Journal of Periodontics & Restorative Dentistry**

**The International Journal of Oral & Maxillofacial Implants**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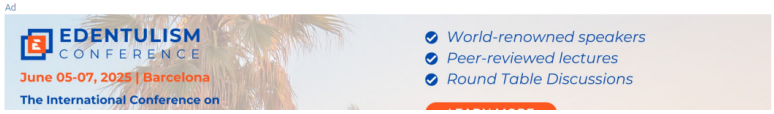

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**100th Annual Greater New York Dental Meeting**
November 29, 2024 — December 4, 2024
New York, United States of America
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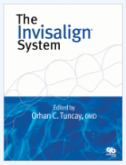


Orhan C. Tuncay (Editor)

## The Invisalign System

1st Edition 2006
Book
Hardcover, 330 pages, 856 illus
Language: English
Category: Orthodontics
Stock No.: BL013
ISBN 978-1-85097-127-6
QP United Kingdom

*Product out of print.*

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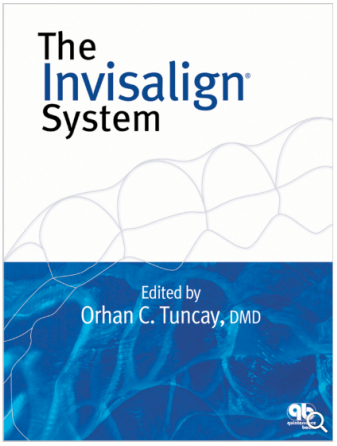


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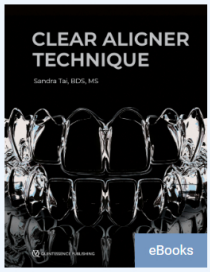


Sandra Khong Tai

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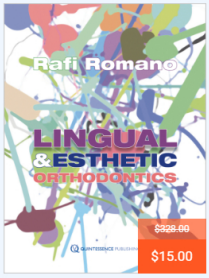


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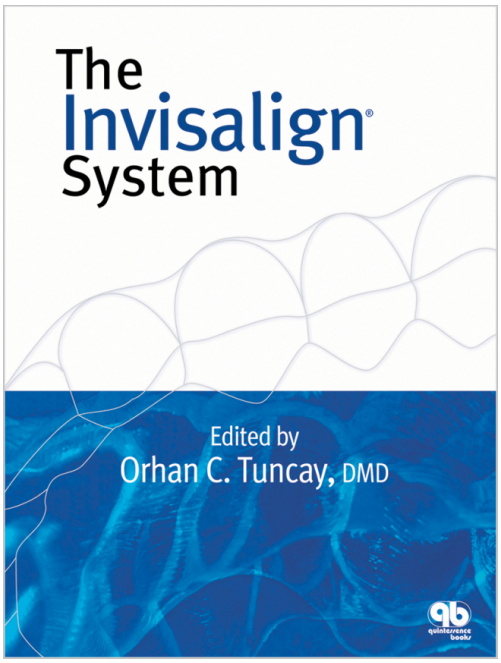


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# Book information

**Editor:** Tuncay, Orhan C.

**Title:** The Invisalign System

**Short text:**

This book, the first to be published on the Invisalign System, provides the reader with an in-depth look at the technology, performance, and clinical applications of this uniquely esthetic and patient-friendly approach to orthodontic treatment. Unlike conventional fixed orthodontic treatment approaches, Invisalign is a system that uses the clinician's diagnostic data to create a three-dimensional image of the desired course of tooth movement; treatment is then carried out using a series of custom-manufactured removable, clear plastic aligners. Full-color images illustrate every step of this process: from impression taking, image acquisition, and virtual diagnosis through digital three-dimensional treatment planning. Clinical considerations, such as indications and contraindications, esthetic analysis, and treatment of adolescents, are also discussed. In addition, the technology behind the Invisalign System - including software, appliance design, manufacturing, material properties, biomechanics of force systems applied to the teeth, and periodontal response to treatment - is presented in the context of how it currently functions as well as research and development for future innovations. Excellent for clinicians who want to learn more about how the Invisalign System can be integrated into their practice.

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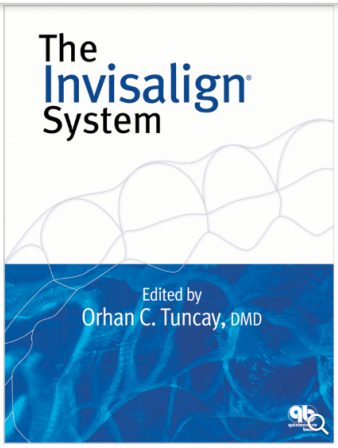


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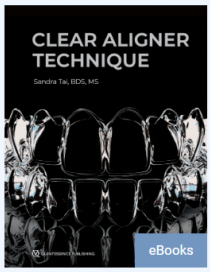


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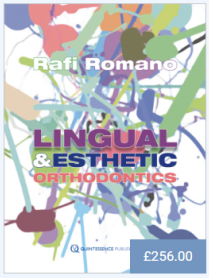


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| **To:** | Hayes Greenhill, Kelley |
| **Subject:** | Re: case #CAS-1432442-S2M0V9: Question about MARC record (NLM MMS_ID 9912853563... TRACKING:000435001450733 |
| **Date:** | Tuesday, February 11, 2025 8:08:44 AM |
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Customer Email: kelley.hayesgreenhill@finnegan.com
Case Created: 2/6/2025, 3:00:01 PM

Summary: Question about MARC record (NLM MMS_ID 9912853563406676)

Details: Hello,

I am trying to find out what the following MARC tag means. I'm in the MARC record for ***The Invisalign System*** [edited by] Orhan C. Tuncay. MARC The Invisalign Systems catalog recordTag 992__ | pP3eE4a20060817. Can you tell what this line means? Is this the date you received the print version of the book?

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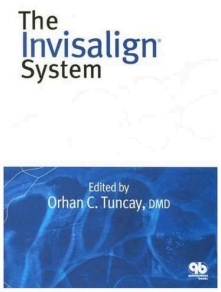


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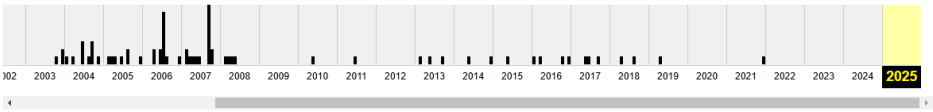


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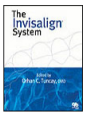
## The Invisalign System

**Orhan C Tuncay**




This book, the first to be published on the Invisalign System, provides the reader with an in-depth look at the technology, performance, and clinical applications of this uniquely esthetic and patient-friendly approach to orthodontic treatment. Unlike conventional fixed orthodontic treatment approaches, Invisalign is a system that uses the clinician's diagnostic data to create a three-dimensional image of the desired course of tooth movement; treatment is then carried out using a series of custom-manufactured removable, clear plastic aligners. Full-color images illustrate every step of this process: from impression taking, image acquisition, and virtual diagnosis through digital three-dimensional treatment planning. Clinical considerations, such as indications and contraindications, esthetic analysis, and treatment of adolescents, are also discussed. In addition, the technology behind the Invisalign System - including software, appliance design, manufacturing, material properties, biomechanics of force systems applied to the teeth, and periodontal response to treatment - is presented in the context of how it currently functions as well as research and development for future innovations. Excellent for clinicians who want to learn more about how the Invisalign System can be integrated into their practice.

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