

# Meeting UDI for Oral Care Products

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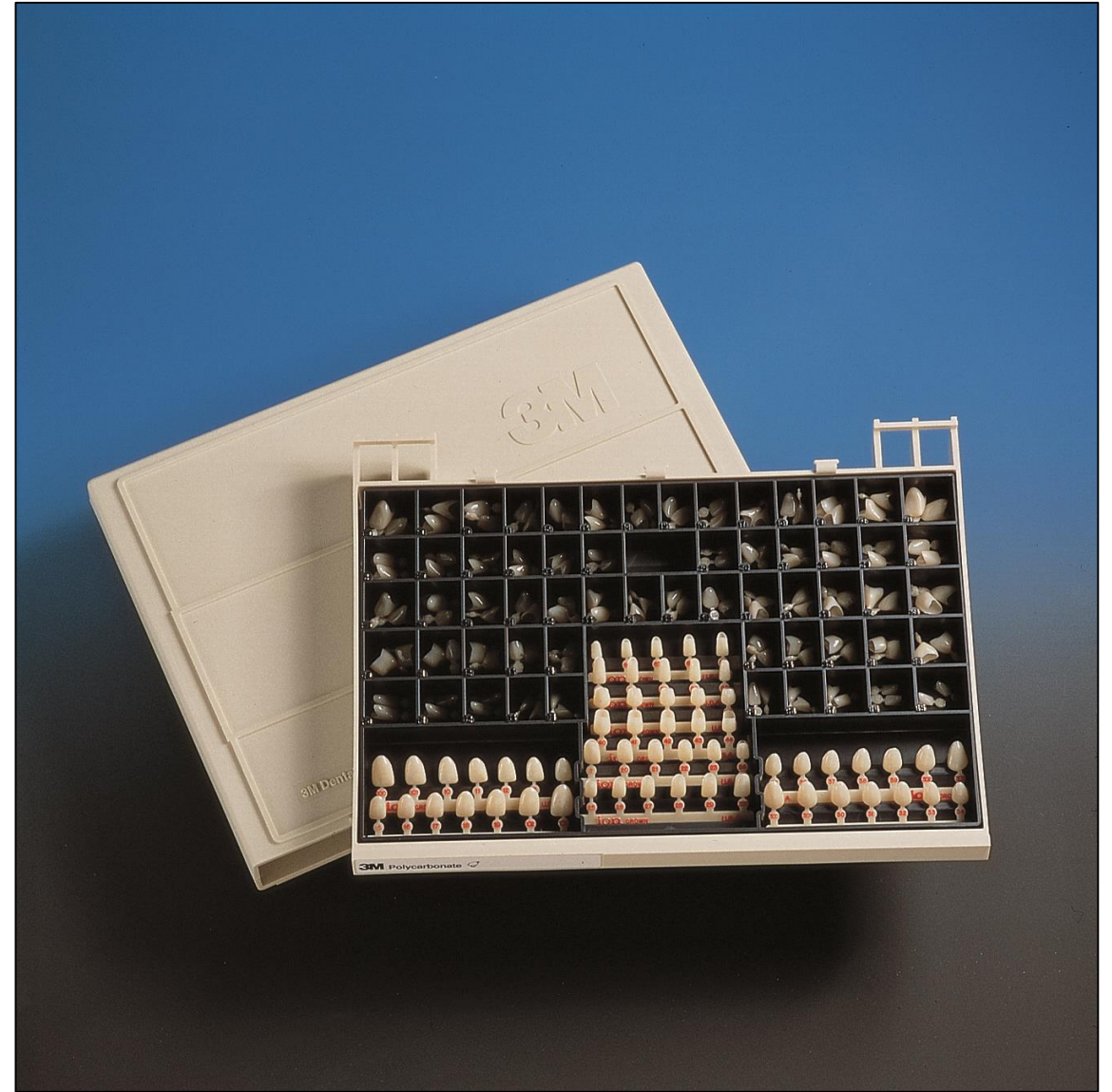
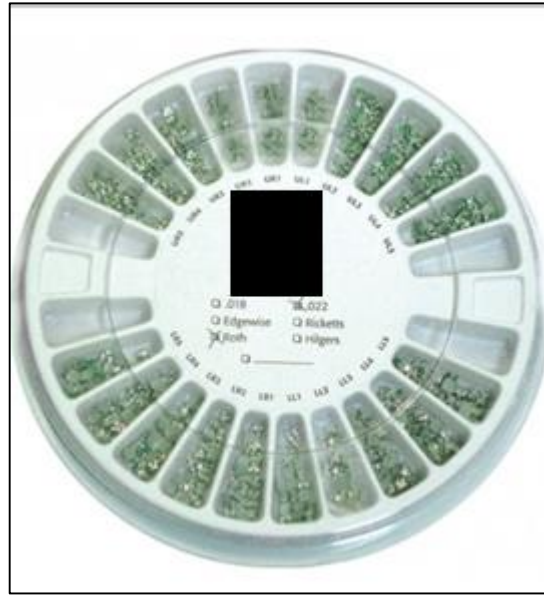
# What is challenging about oral care?



- The mouth
  - Small, dark, wet
  - Microbiologically active
  - Changes throughout life
- The products
  - Cure inside the mouth
  - Highly customized
  - Require large inventory
  - Very small package sizes
- The regulatory model varies globally
- The business model varies globally
  - Cosmetic focus
  - Small business owners in some countries
  - Inconsistent coverage

# Storage Considerations

- Reusable organizers
- Bulk storage
- Mixed inventory
- Small parts for marking or tagging



# Technical Considerations



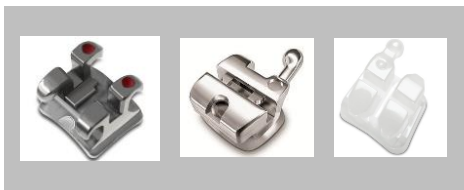
- Size - AIDC vs. HRI
- Manufacturing Processes – tube seal



- Contrast
- Curvature
- Disinfection



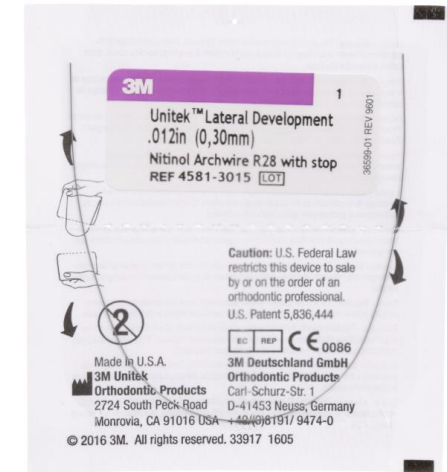
- Size
- Uneven surface
- Safety – microbial host



- Manufacturing Processes – blister seal
- Reflection

# Potential solutions

- Change how the product is stored or sold
  - Attach orthodontic wires to cards, use resealable pouches/boxes
- Change the production order to prepare the label earlier
- Invert contrast
  - Consider laser off a black box vs. printing on a substrate
- Use laser sensitive pigments into plastic materials
- Add labels or tags
- Change the AIDC shape for highly curved products



Square



Rectangle



Have robust documentation of technical feasibility and use cases when you need to discuss these challenges with regulators. Offer alternative solutions not problems.



UDI Data

# Device Count – Product Design

- Multi-component products
  - Single product license/registration, multiple packages
  - Sometimes sold as refills
- Products with accessories
  - Reusable parent product, disposable accessories
- Data questions:
  - Is the device count = 1?
  - Can manufacturers enter more than 1 GTIN for the each/unit of use level?
  - Do we use the “parent device” characteristics?



# Device Count – Complex Configurations

- No shared regulatory definition of a kit
  - Procedure kit
  - Convenience kit
  - Product introduction kit
  
- Data questions:
  - Is this product a “kit” in Country X?
  - How do I maintain accurate data for these different definitions?





# Data Management



## Listen

- Who is asking for data?
- How are they using the data?
- Can they clearly define the attributes?



## Influence

- Participate in trade organizations
- Drive global, harmonized standards



## Adapt

- Make decisions
- Document rationale and justification
- Stay flexible for changes



Questions?