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CELL & GENE BIOTECHNOLOGY

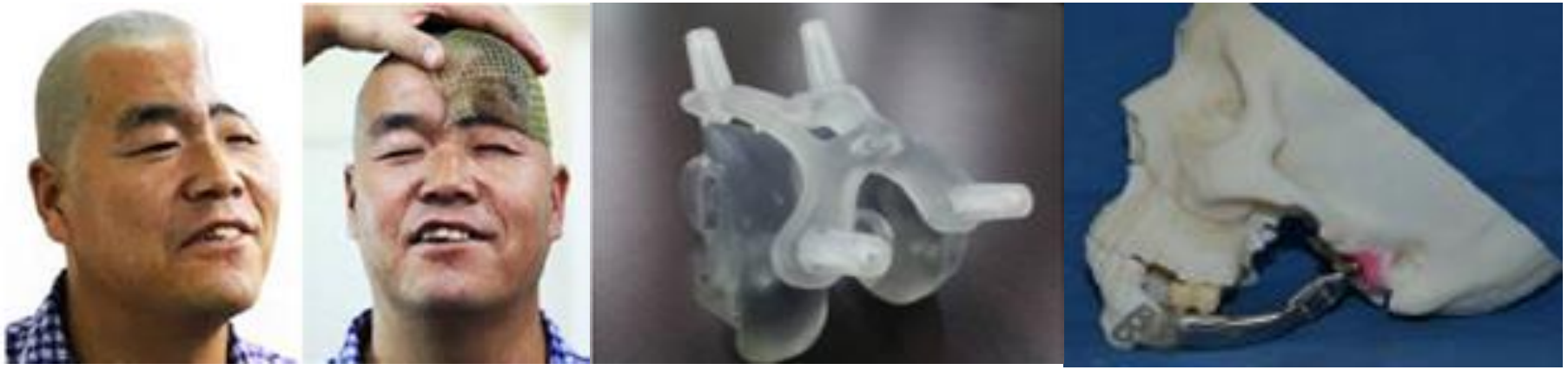
Patient Specific Medical Devices Based on 3D Printing Technology

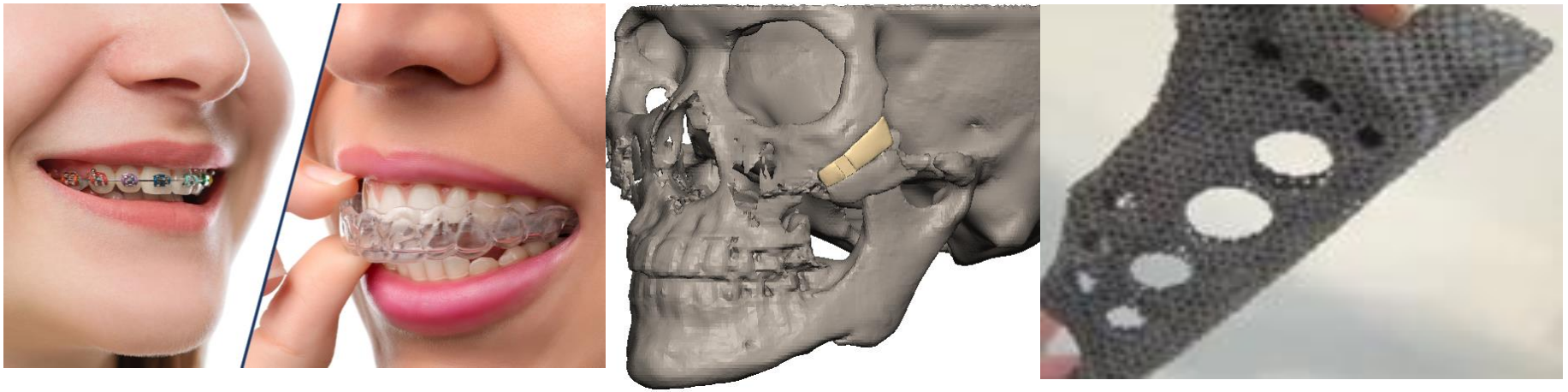
Jun Young, Lim

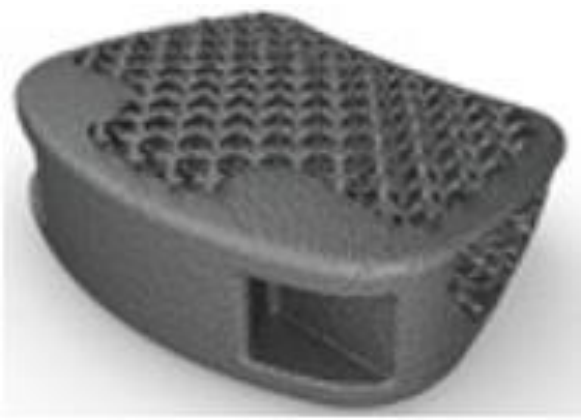
3D Innovation Center

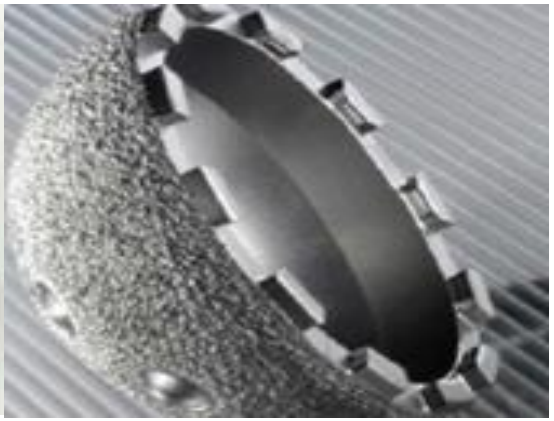


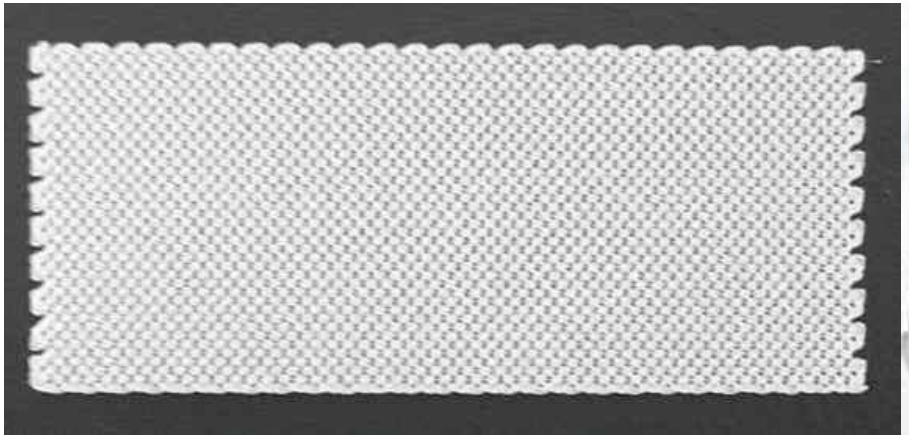


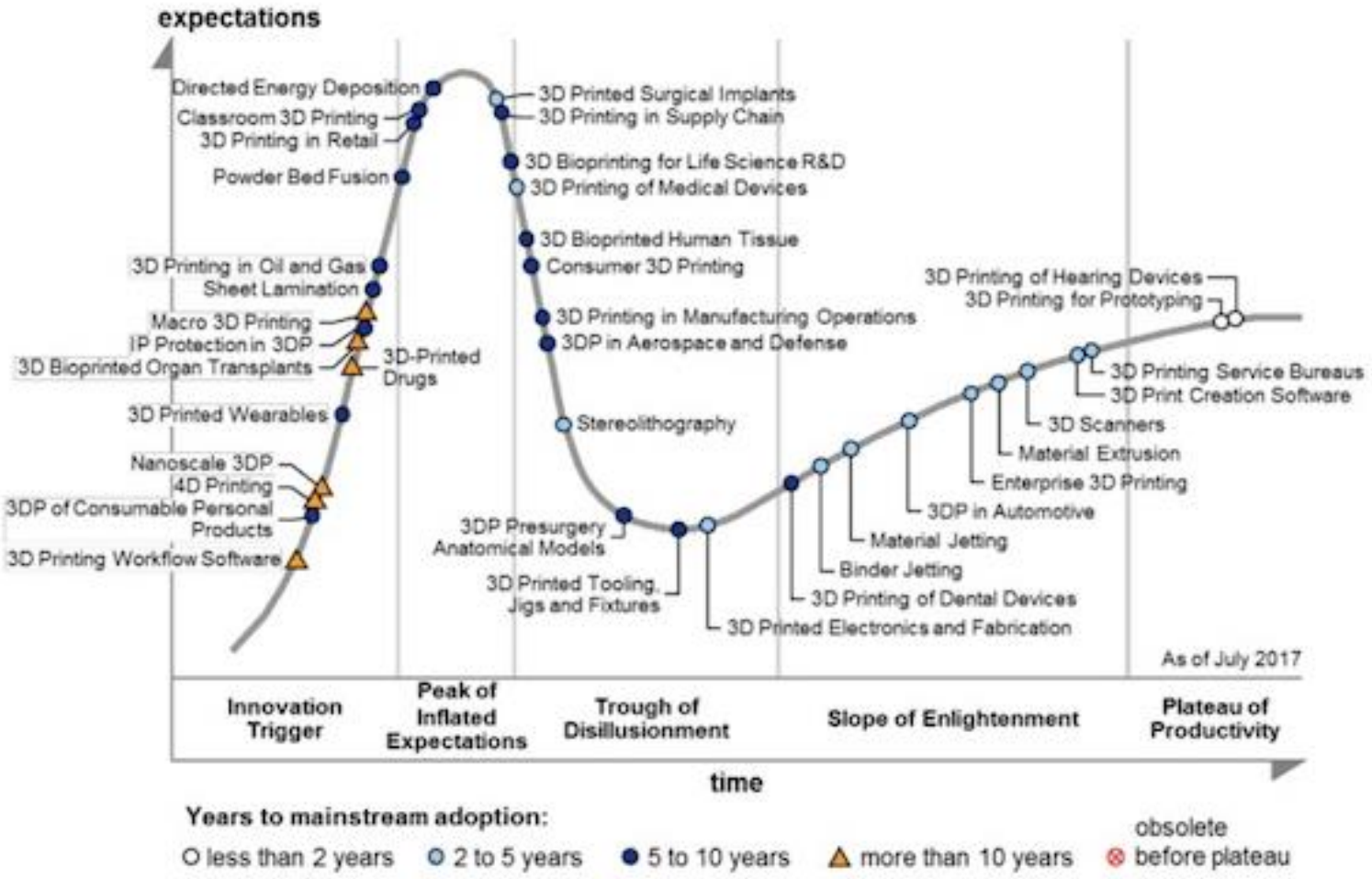












expectations
Directed Energy Deposition
Classroom 3D Printing
3D Printing in Retail
Powder Bed Fusion
3D Printing in Oil and Gas
Sheet Lamination
Macro 3D Printing
IP Protection in 3DP
3D Bioprinted Organ Transplants
3D-Printed Drugs
3D Printed Wearables
Nanoscale 3DP
4D Printing
3DP of Consumable Personal Products
3D Printing Workflow Software
3D Printed Surgical Implants
3D Printing in Supply Chain
3D Bioprinting for Life Science R&D
3D Printing of Medical Devices
3D Bioprinted Human Tissue
Consumer 3D Printing
3D Printing in Manufacturing Operations
3DP in Aerospace and Defense
Stereolithography
3DP Presurgery Anatomical Models
3D Printed Tooling, Jigs and Fixtures
3D Printed Electronics and Fabrication
3D Printing of Dental Devices
Binder Jetting
Material Jetting
3DP in Automotive
Enterprise 3D Printing
Material Extrusion
3D Scanners
3D Print Creation Software
3D Printing Service Bureaus
3D Printing for Prototyping
3D Printing of Hearing Devices
As of July 2017
Innovation Trigger
Peak of Inflated Expectations
Trough of Disillusionment
Slope of Enlightenment
Plateau of Productivity
time
Years to mainstream adoption:
less than 2 years
2 to 5 years
5 to 10 years
more than 10 years
obsolete before plateau

3D Printing of Medical Devices
Medical Applications of 3D Printing
Process of 3D Printing Medical Devices
FDA's Role in 3D Printing

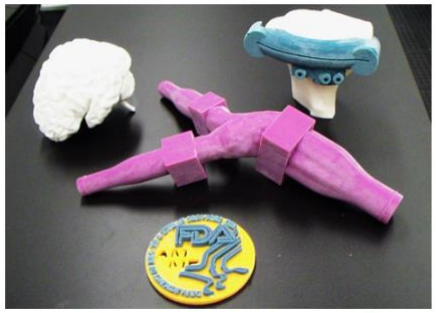
3D Printing of Medical Devices

Overview

3D printing is a type of additive manufacturing. There are several types of additive manufacturing, but the terms 3D printing and additive manufacturing are often used interchangeably. Here we will refer to both as 3D printing for simplicity.

3D printing is a process that creates a three-dimensional object by building successive layers of raw material. Each new layer is attached to the previous one until the object is complete. Objects are produced from a digital 3D file, such as a computer-aided design (CAD) drawing or a Magnetic Resonance Image (MRI).

The flexibility of 3D printing allows designers to make changes easily without the need to set up additional equipment or tools. It also enables manufacturers to create devices matched to a patient's anatomy (patient-specific devices) or devices with very complex internal structures. These capabilities have sparked huge interest in 3D printing of medical devices and other products, including food, household items, and automotive parts.



3D printed (left to right, top) models of a brain, blood vessel, surgical guide, and (bottom) medallion printed on FDA 3D printers.

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Medical Devices
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3D Printing of Medical Devices
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FDA's Role in 3D Printing

FDA's Role in 3D Printing

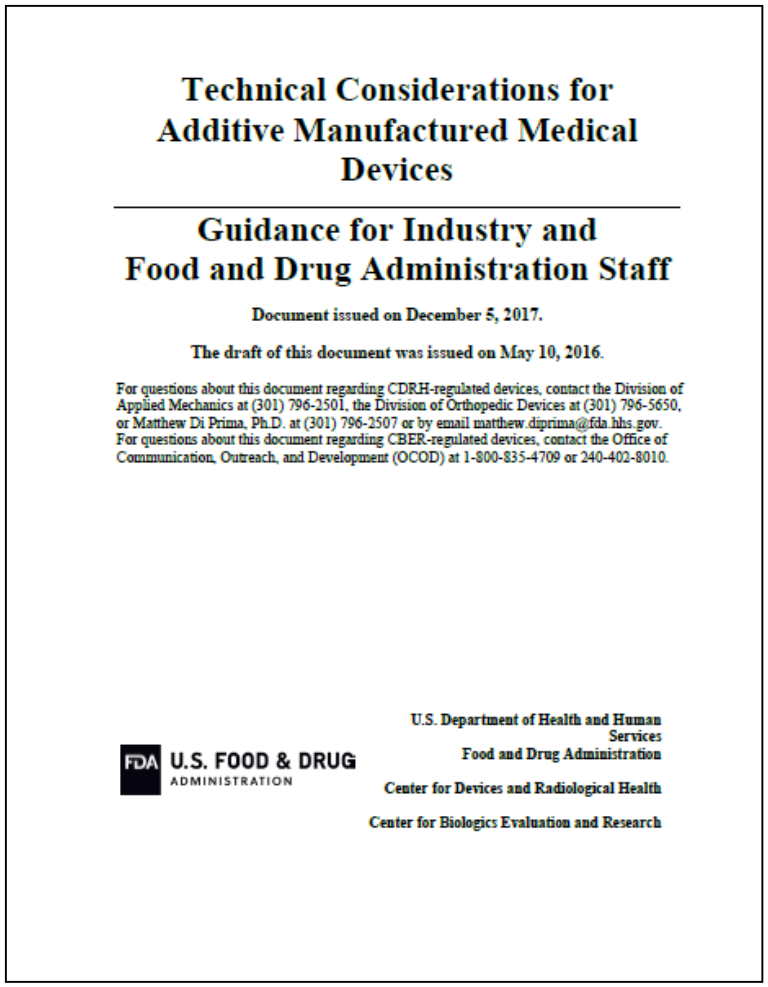
The FDA's Center for Devices and Radiological Health (CDRH) regulates firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States.

Like devices made using other manufacturing processes, devices made using 3D printing technology are subject to regulatory requirements. Some requirements apply to medical devices before they are marketed (premarket requirements), and others apply to medical devices after they are marketed (postmarket requirements). Medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval. A description of device classification and a link to the Product Classification Database is available at: Classification of Medical Devices.

In 2016, the FDA issued draft guidance on the Technical Considerations for Additive Manufactured Devices to advise manufacturers who are producing devices through 3D printing techniques. This draft guidance has been published to obtain public feedback and is not final or in effect at this time. The FDA is currently evaluating submissions for new 3D printed medical devices to determine safety and effectiveness. The draft guidance provides manufacturers with recommendations for device design, manufacturing, and testing considerations when developing 3D printed devices. The type of premarket submission required for a device is still determined by its regulatory classification.

This draft guidance is broadly organized into two topic areas:

- **Design and Manufacturing Considerations:** This section of the guidance provides technical considerations that should be addressed as part of fulfilling Quality System (QS) requirements for a device, as determined by its regulatory classification or regulation to which it is subject, if applicable. While this draft guidance includes manufacturing considerations, it is not intended to comprehensively address all considerations or regulatory requirements to establish a quality system for the manufacturing of a device.
- **Device Testing Considerations:** This section of the guidance describes the type of information that should be provided in premarket notification submissions [510(k)], premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, de novo requests and investigational device exemption (IDE) applications for a 3D printed device.



Technical Considerations for Additive Manufactured Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 5, 2017.

The draft of this document was issued on May 10, 2016.

For questions about this document regarding CDRH-regulated devices, contact the Division of Applied Mechanics at (301) 796-2501, the Division of Orthopedic Devices at (301) 796-5650, or Matthew Di Prima, Ph.D. at (301) 796-2507 or by email matthew.diprima@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

FDA U.S. FOOD & DRUG ADMINISTRATION

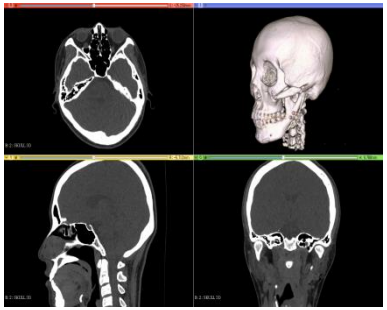
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Design & Manufacturing Process Consideration

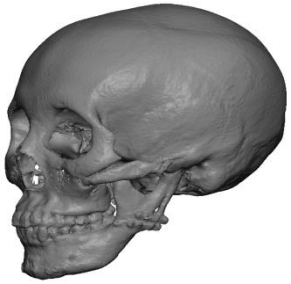
A. Device Design
B. Software Workflow
C. Material Control
D. Post Processing
E. Process Validation
F. Quality Data

Device Testing Consideration

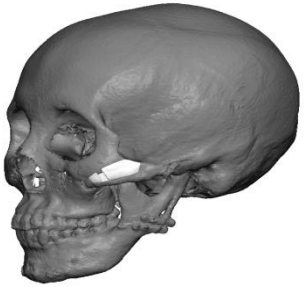
A. Device Description
B. Mechanical Testing
C. Dimensional Measurements
D. Material Characterization
E. Removing Manufacturing Material & Sterilization
F. Biocompatibility



CT or MRI Data

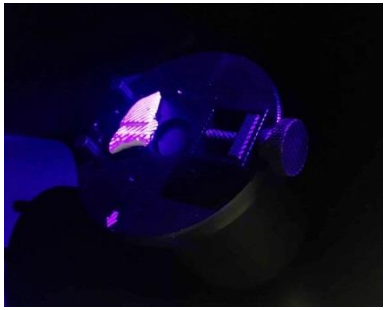


3D Rendering

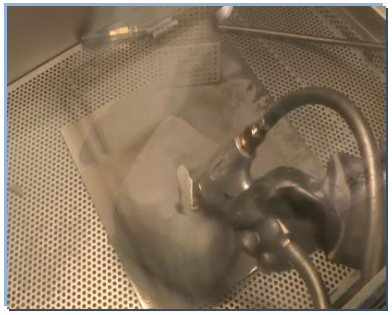


Implant Design

3D Printing



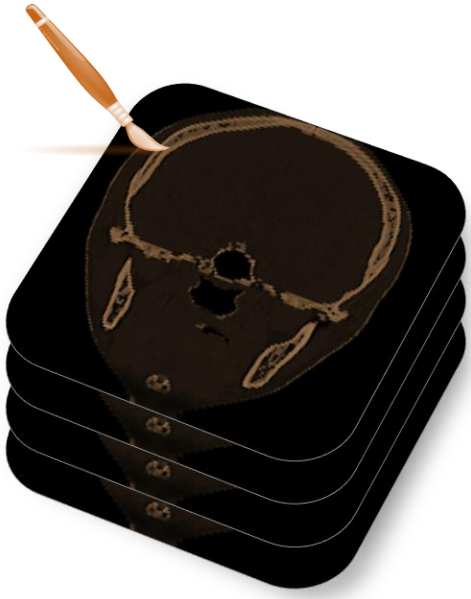
3D Scanning
Implant Inspection



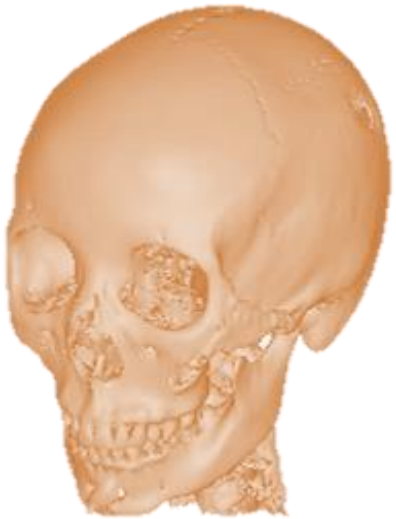
Sterilization &
Cleaning

Application in
Surgeries

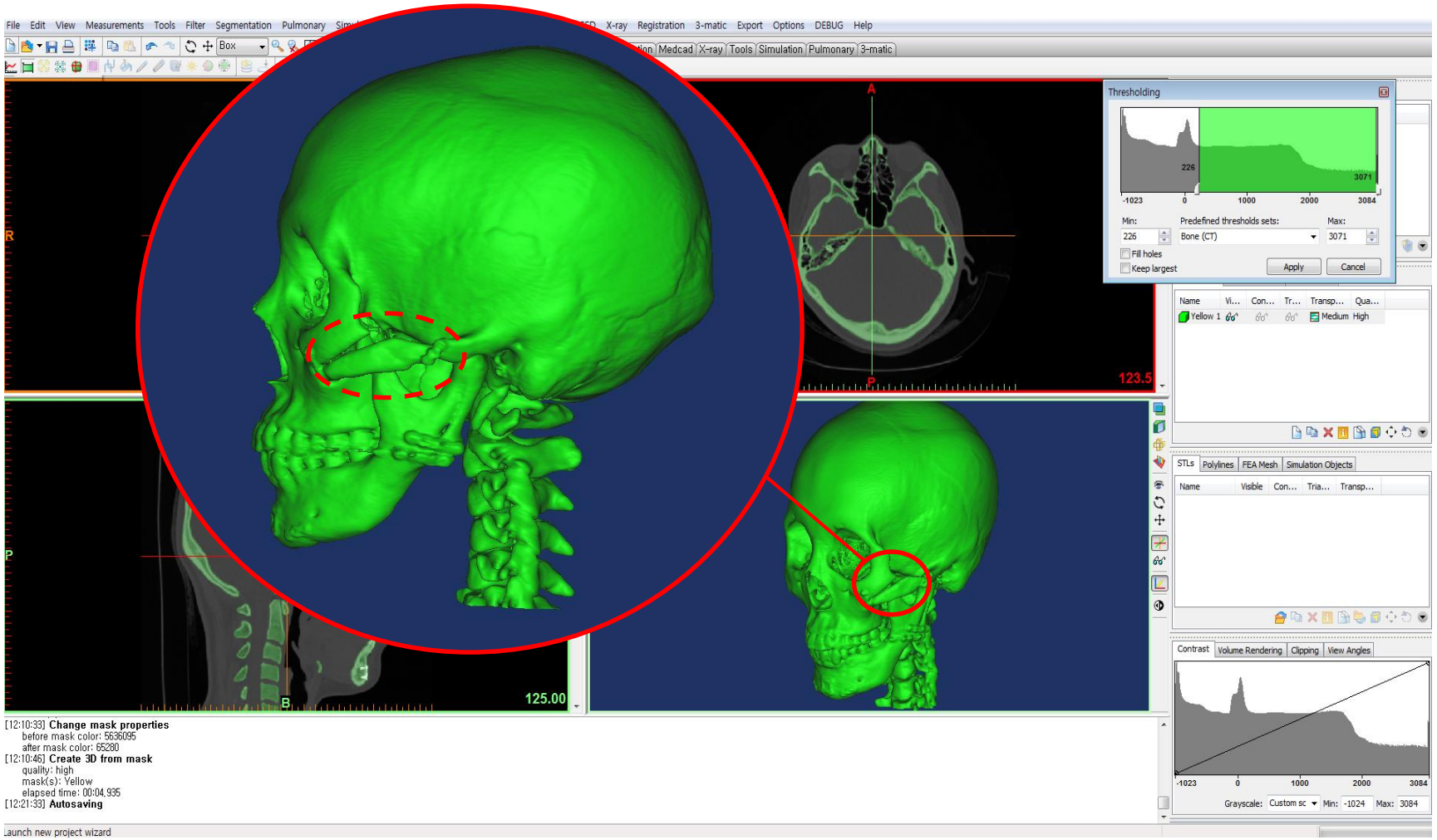
Medical Data(CT/MRI)



Segmentation(Drawing)



3-Dimensional
(Rendering)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Medcad X-ray Tools Simulation Pulmonary 3-matic
Thresholding
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3071
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Min: 226
Predefined thresholds sets: Bone (CT)
Max: 3071
Fill holes
Keep largest
Apply
Cancel
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Yellow 1 Medium High
STLs Polylines FEA Mesh Simulation Objects
Name Visible Con... Tria... Transp...
Contrast Volume Rendering Clipping View Angles
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after mask color: 65280
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mask(s): Yellow
elapsed time: 00:04.935
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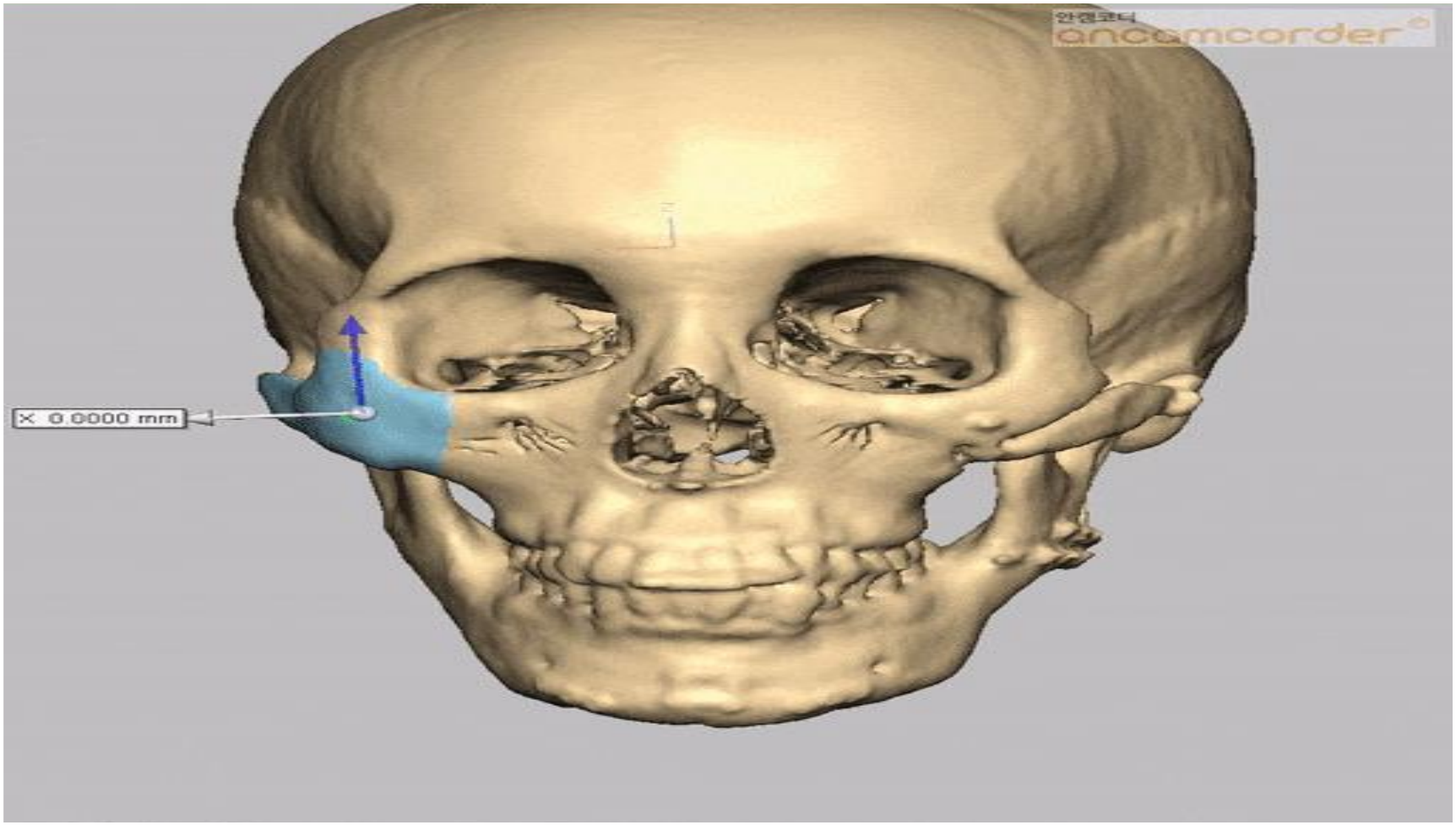
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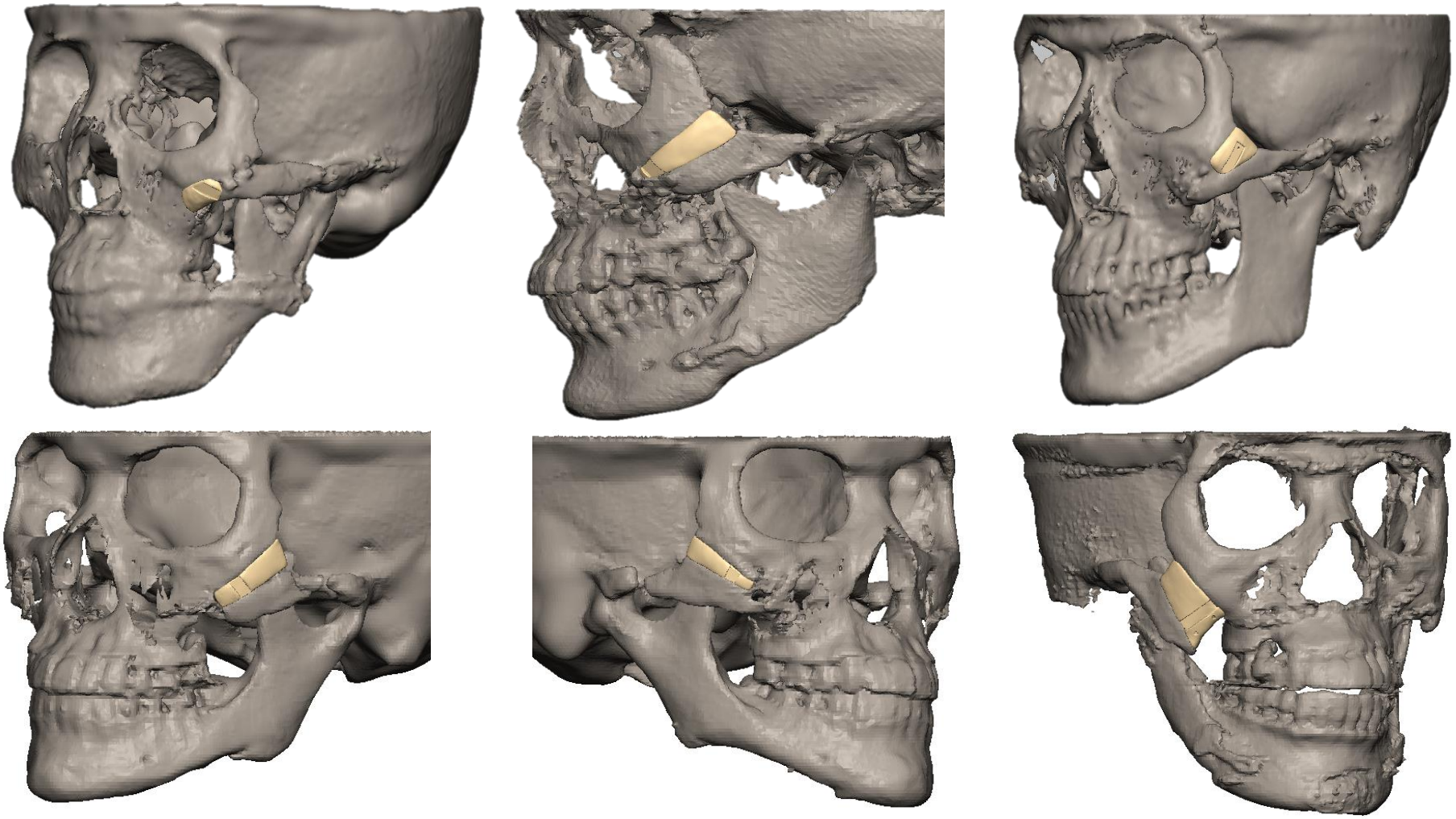
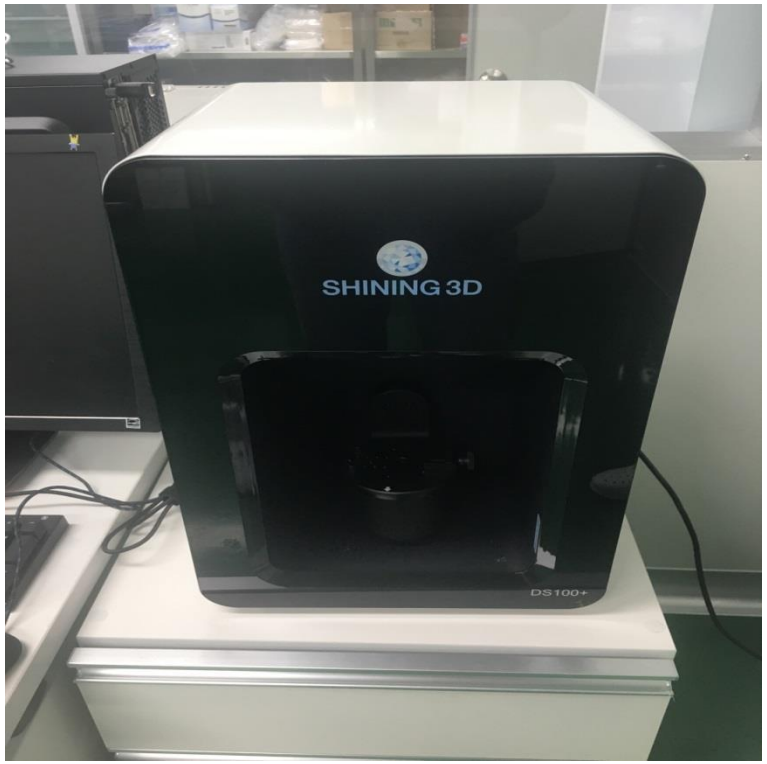
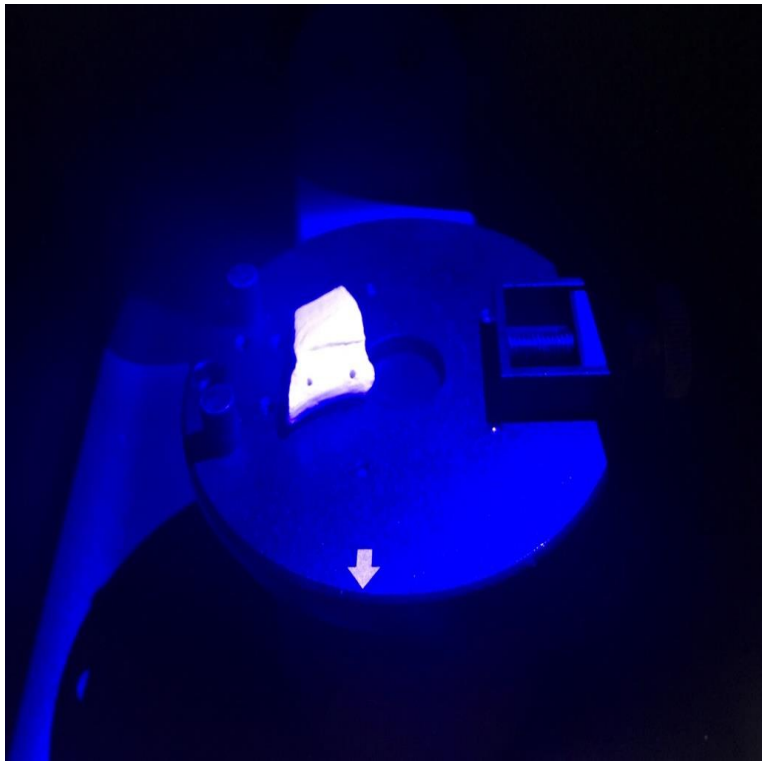
Design Process



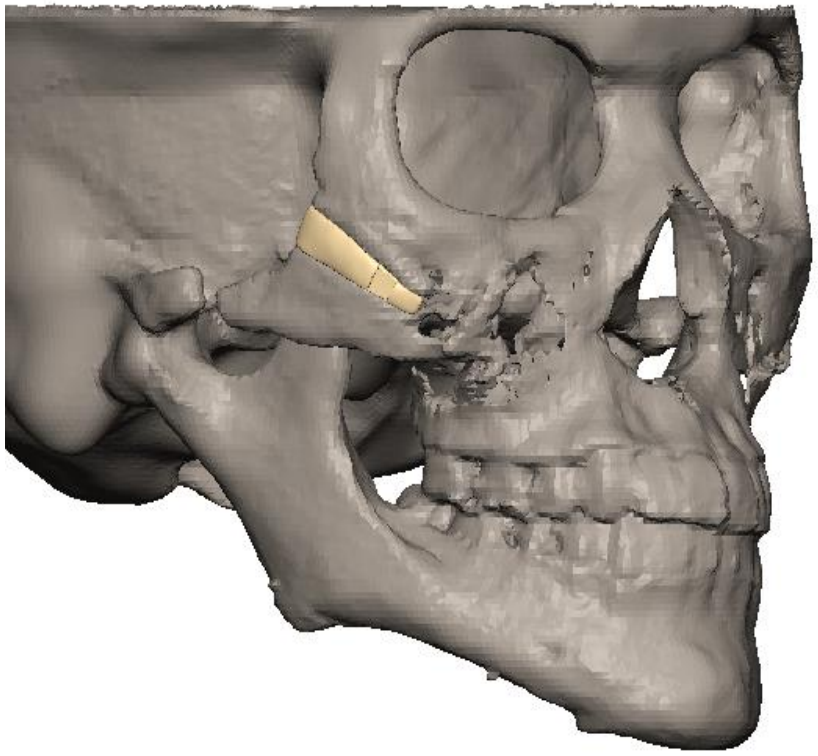
3D Scanner

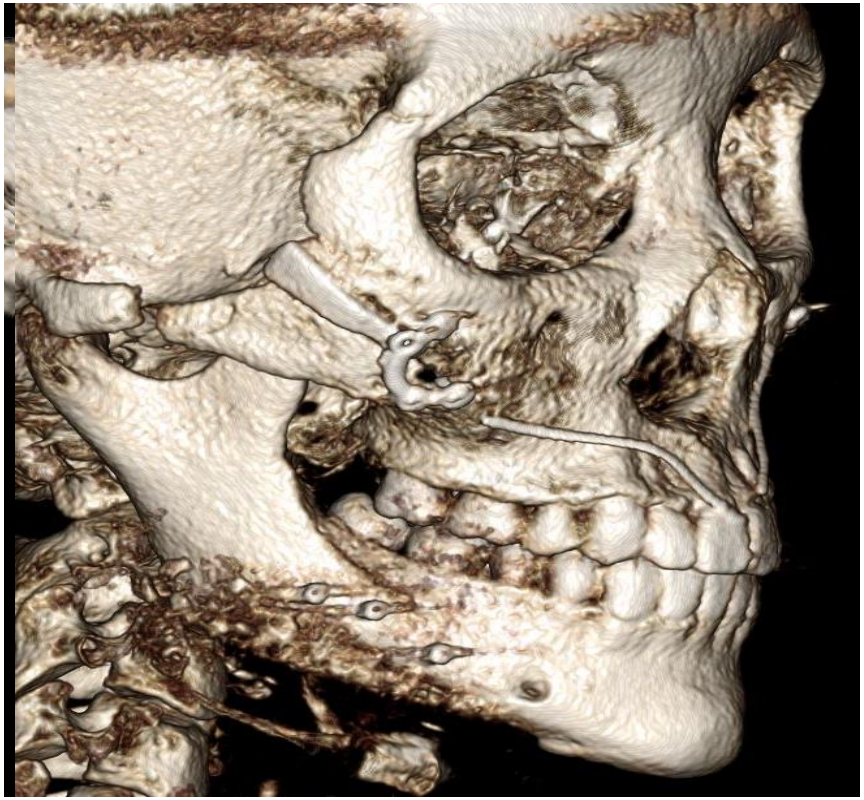


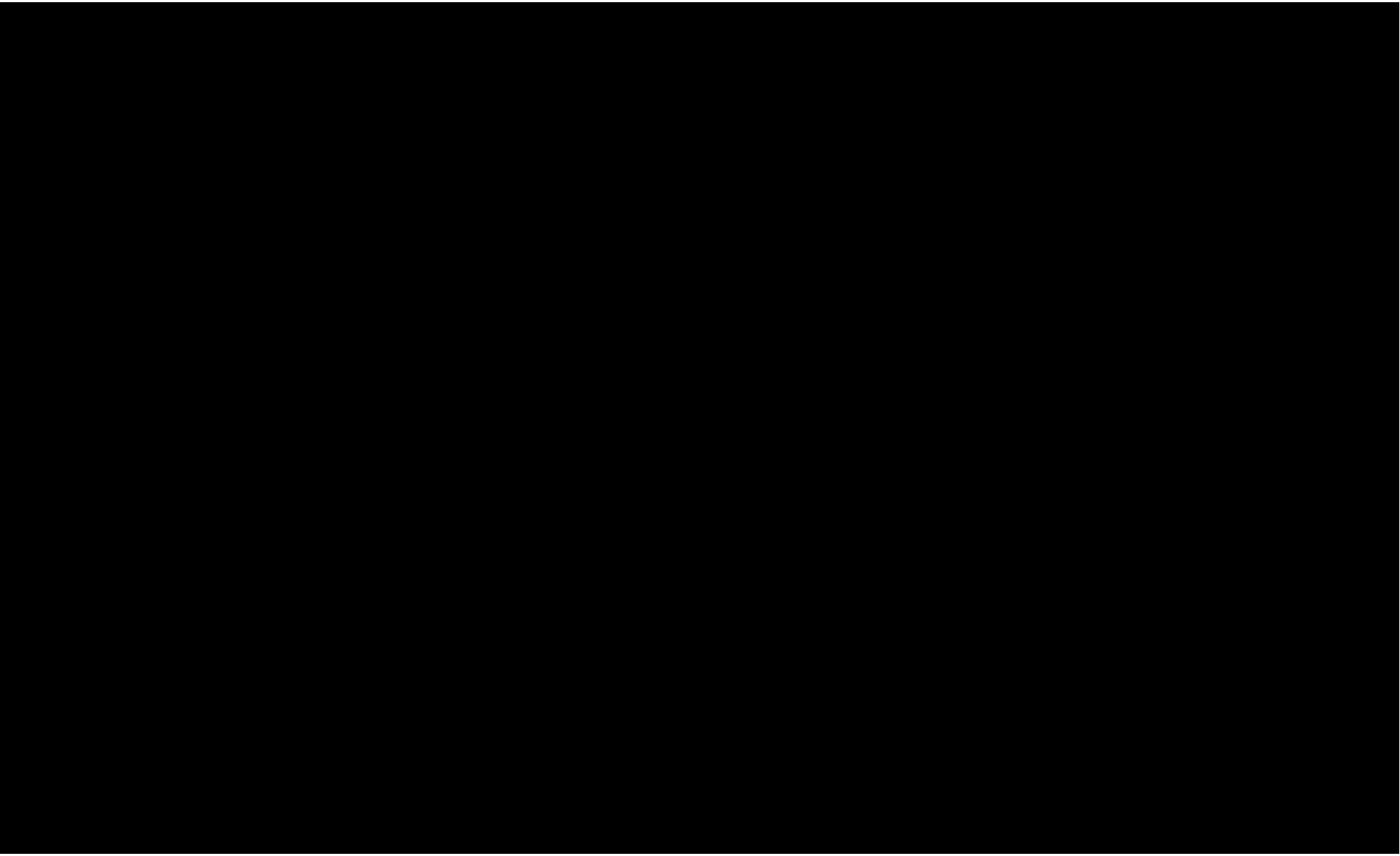


Sterilization &Cleaning

Clinical trial







THANK YOU

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