# Medical 3D Printing Solution







# AI-Powered Digital Twin

At the intersection of technology and the clinical expertise, we have been leading the paradigm change of medical imaging solution with reliable AI imaging analytic and Digital Twin technology. Experience unprecedented imaging solution and Transform your Medicine!



# **Product Information**

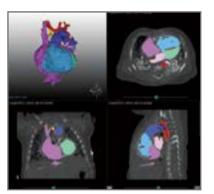
Surgical planning 00	Surgic	al pl	anni	ng	06
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# Our Spirit & Endeavour

MEDICAL IP strives to develop technologies and products with the philosophy that technological innovation is directly connected to the development of medical care and saving lives. We support UN Sustainable Development Goals (SDGs) to achieve our mission and responsibilities.

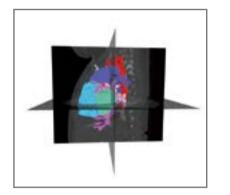








MEDICAL IP's own segmentation and analysis software





Medical Communication

# **3D PRINTING** SOLUTION WORKFLOW

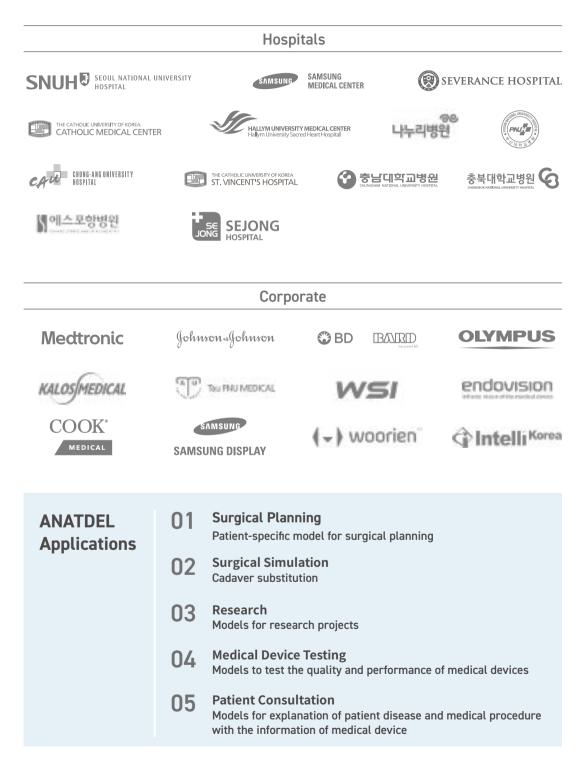
MEDICAL IP delivers patient specific 3D printing model within a week



Medical 3D Printing

# ANATDEL is a *"life-saving"* technology

# **Gartner** 5 consecutive years. sample vendor 3D Printed Presurgery Anatomical Models



# **Surgical Planning**

# **Pediatric Congenital heart defects**

Medical Device Info. refer to 26p



36

Male

CT 2 mm

Urology ABS, Silicone

169 × 80 × 103 mm

AN-KDTPC-19096 RCCPNS-001

kidney, vein, artery, tumor, calyx

Renal cell carcinoma

Age Sex

Disease

Source

Application

Printed area

Model No.

Item No.

Material

Size

- Age Sex Disease Source
- 5 Female Major aortopulmonary collateral artery CT 0.6 mm



Application Material Size Printed area Model No. Item No. Pediatric cardiac surgery Resin 93×64×115 mm heart, aorta, pulmonary vessels AN-HTMPP-19002 PCHS-BH-001

# ☑ Renal cell carcinoma



7

# Arteriovenous malformation



# ✓ NeuroPhantom<sup>™</sup>



71 Male Brain tumor MR 1mm

Age

Sex Disease

Source

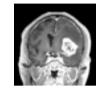
Application Material

Printed area

Model No.

Item No.

Size



Neurosurgery Resin, ABS, Silicone 165 × 152 × 174 mm cerebrum, cerebellum, lateral ventricle, tumor AN-BRTRC-19001 BCS-001





Age Sex Disease Source



24

Male

AVM

CT 0.5mm

Application Material Size Printed area Model No.

Plastic surgery Resin 130 × 113 × 201 mm vein, artery, bone AN-FCMPP-19001

Age	
Sex	
Disease	
Source	

Size

63 Female Brain tumor MR 2 mm



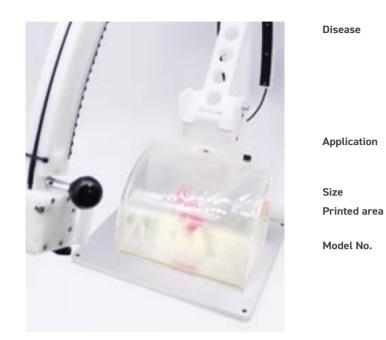
Application Material Printed area Model No. Item No.

Neurosurgery Resin, ABS, Silicone 165 × 152 × 174 mm cerebrum, cerebellum, lateral ventricle, tumor AN-BRTRC-19005 BCS-001



# Surgical simulation

# Percutaneous nephrolithotomy simulator



Kidney stones



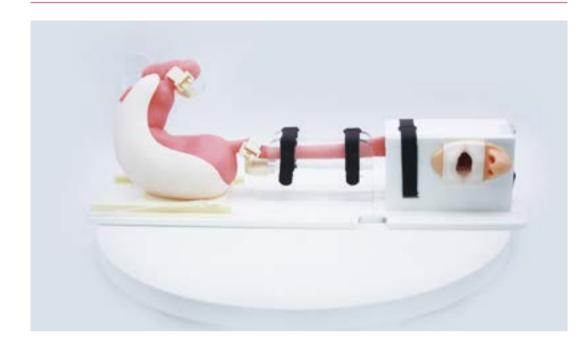
Training for defining puncture direction, dilation and stone 250 × 150 × 150 mm kidney, renal pelvis, renal calyx, ureter AN-KDCTC-20001

# Toxin & filler injection simulator

Application	Training for Facial toxin	
	and filler injection skill	
Size	170x250x110 mm	
Printed area	skin, subcutaneous fat,	
	muscle, artery, vein, nerve	
Model No.	AN-PSNTC-21001	



# Upper Gastrointestinal Endoscopy simulator



# Lumbar spinal surgery training simulator







Application

Size

Printed area

Model No.



Training for navigation of endoscope from mouth insertion to duodenum 584 × 255 × 250 mm face, tongue, pharynx, larynx, epiglottis, pyriform

sinus, esophagus, trachea, stomach, duodenum AN-GINTC-20003





Disease

Surgical training for

discectomy at Lumbar

Herniated disc

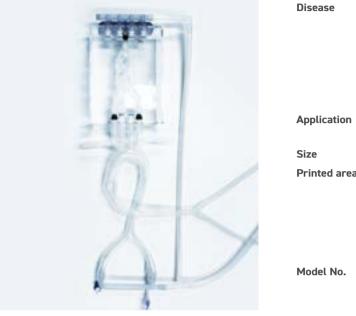
Application

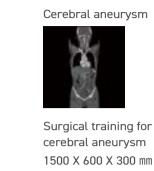
Size Printed area 350 × 300 × 200 mm vertebra, sacrum, ilium, disc (anulus fibrosus / nucleus pulposus), spinal cord(dura master / spinal nerve), psoas, iliacus, inter spinous ligament, supraspinous ligament, ligamenta flava, anterior longitudinal ligament, articular capsule of lumbar spinal cord AN-SPMTC-19002



Model No.

# EndoVascular Simulation Station





artery

regular version: ACA, MCA, PCA, ICA, basilar artery, vertebral artery, Aorta, femoral

Ver. 2: Hepatic artery AN-LVNTC-22001

Printed area

Model No.

# Skull base surgery simulator

Disease



Training for skull base Application

Size Printed area

Model No.

surgery 150 × 100 × 90 mm skull, cerebrum, cerebellum, pituitary gland, stalk, pons, medulla oblongata, CN1, CN2, CN3, CN5, CN6, CN4, CN7,CN8, tumor, muscle, basilar plexus, vein, artery eyeball, ica, eca, dura mater, soft tissue, skin AN-HDTTC-20001



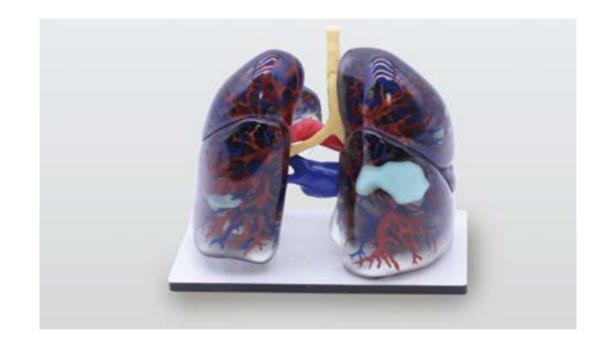




# ☑ Neuro aneurysm



# COVID-19 lung





Age Sex



Disease Source

> Application Material Size Printed area

Model No.



59



Neurosurgery Resin, Plaster 120 × 120 × 70 mm skull, brainstem, artery(thrombosed), vein, tentorium AN-BRXRP-20005



Age Sex Disease Source

42 Female COVID-19

CT 1 mm



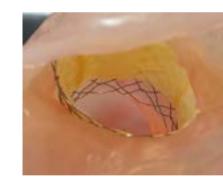
Application Material Size Printed area Model No.

Respiratory Medicine, infectious diseases Resin 280 × 200 × 230 mm lung, trachea, bronchus AN-LUPDP-20001

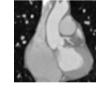
# **Device testing**

# Stent placement for the heart









Model for Test model of Stent Placement for the Heart 91 × 106 × 107 mm pulmonary trunk, right ventricle AN-HTMVP-19001

Application

Printed area

Model No.

Size

# Tympanostomy in adhesive otitis media simulator





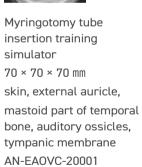


Application

Size

Printed area

Model No.

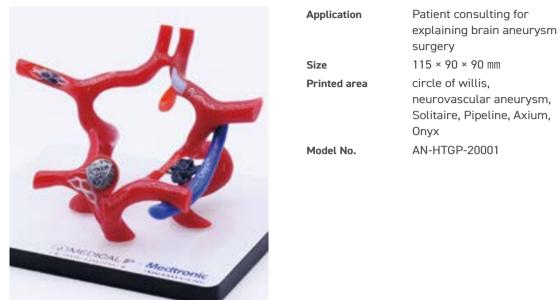


# UD.

# **Patient consultation**

20

# Post-operation model for neurovascular devices



	surgery
	115 × 90 × 90 mm
d area	circle of willis,
	neurovascular aneurysm,
	Solitaire, Pipeline, Axium,
	Onyx
No.	AN-HTGP-20001

# Post-op model of trans-catheter aortic heart valve



# Post-operation model of endovascular aortic aneurysm repair devices

1

2

Medtronic



Application	Patient consulting for explaining brain aneurysm	
	surgery	
Size	① 110x110x150 mm	
	② 100x100x100 mm	
Printed area	abdominal aorta, applier,	
	Heli_FX(fixation), graft	
Model No.	① AN-AVANEC-20001	
	② AN-AVANEC-21001	

Medtronic









trans-catheter aortic heart valve surgery 110 X 125 X 125 mm Aorta, Atrium, Tricuspid Valve, Mitral Valve, Interventricular Septum, Chordae Tendineae, Ventricle, Papillary Muscles, Inferior Vena Cava, Pulmonary Veins AN-HTADP-22001

Patient consultation for

Model No.

Application

Printed area

Size

# Licenses and Certifications

(last updated on Oct. 7th 2022)

# Licensure

Product name	ANATDEL
Country	S. Korea
Item code and level Name of product Product permit number	- Item code and level: A64050.01, level 1 - Name of product: (Kor) 의료용가이드 (Eng) Guide for medical use - Product permit number: 20-1461
Effective date	Sept 24th 2020

# Certification

	Certification number	Effective date
Medica device manufacturer certification	5529	Nov. 14th 2016
Certificate of GMP standards and regulations for Medical Device Manufacturing	KTL-ABBA-7444 * Certificate no.	Feb 1st 2020 – Jan. 31st 2023
EN ISO 13485:2016	SX 60145134 0001	Dec. 27th 2019 – Oct. 31st 2022
EC Certificate	HD 60145133 0001	Dec. 27th 2019 – May 26th 2024 * Surveillance audit completed on Jun 13th 2022

# Clinical Validation | Publication

# 1. Clinical application of 3D virtual and printed models for cerebrovascular diseases

The virtual and printed models of IAs, a CM and AVM were satisfactorily implemented in this study. The physicians easily saw how helpful the human skull model was for the craniotomy and surgical approach. 3D modeling goes beyond a simple skull model and helps to intuitively observe various intracranial structures, such as the brain, vessels and pathologic lesions. In the near future, substantial progress is expected to be made in the neurosurgical field in terms of education, training, explanation and treatment, although there are still some limitations in the imaging data, materials and 3D modeling techniques.

# 2. Clinical application of patient specifc 3D printing brain tumor model production system for neurosurgery

We established a 3D-printed brain tumor model production system that is ready to use in daily clinical practice for neurosurgery. The effectiveness of this system was tested in clinical field and could be confirmed by simulated clinical validation. We hope that this system will be widely introduced to the neurosurgery clinic as a new gear for the development of the next step for the future surgery.

# 3. Personalised three-dimensional printed transparent kidney model for robot-assisted partial nephrectomy in patients with complex renal tumours (R.E.N.A.L. nephrometry score >7): a prospective case-matched study

The application of a personalised 3D-printed transparent kidney model during RPN reduced the console time by ~20% even in complex renal tumours. In particular, we found a substantial reduction in the tumour detection and dissection time step. In more complex tumour subgroups, we also found significant benefits in specific step times. In conclusion, the 3D-printed kidney model is useful as a surgical navigator for RPN and is expected to broaden the indications for PN.

# 4. Utility of three-dimensional printed heart models for education on complex congenital heart diseases

The utilisation of three-dimensional printed heart models for education on complex congenital heart disease was feasible and improved medical personnel's understanding of complex congenital heart disease. This education tool may be an effective alternative to conventional education tools for complex congenital heart disease.

## Reference

1) Clinical application of 3D virtual and printed models for cerebrovascular diseases, Volume 206, July 2021, Clinical Neurology and Neurosurgery

2) Clinical application of patient-specific 3D printing brain tumor model production system for neurosurgery, 26 March 2021, Scientific Reports

 Personalised three-dimensional printed transparent kidney model for robot-assisted partial nephrectomy in patients with complex renal tumours (R.E.N.A.L. nephrometry score >7): a prospective case-matched study,2021 May;127(5):567-574, BJU international

4) Utility of three-dimensional printed heart models for education on complex congenital heart diseases, Nov 2020, Cardiol Young

# Medical Device Labeling

# 01\_ ANATDEL

- 02\_ Product Name Clinical Guide
- 03\_ Model Number BCS-001 and 14 other types

# 04\_ Manufactured by

MEDICAL IP, Inc. Headquaters: 1204-ho, Bodeum Building, 1, Kangwondaehak-gil, Chuncheon-si, Gangwon-do Office: 801-6-ho, Yeongeon 32-dong, 101, Daehak-ro, Jongno-gu, Seoul

- 05\_ Manufacture Number, Date of Manufacture Confirming Notes after Product Manufacture
- 06\_ Product License Number Jeshin No. 17- 4141

07 Purpose of Use

An instrument to guide the path, location, and indication of the surgical site of an implant or a device. However, invasive-type disposables and dental uses are excluded

- 08\_ How to Use, Use Precautions See the User Manual
- 09\_ Package Unit 1set
- 10\_ This device is a single-use, patient-customized medical device
- 11\_ Other characteristics of the device related to technical information See the User Manual
- 12\_ How to Store
  - \* Store at room temperature
  - \* Where to attach: attach additional information at the bottom of the back of device

# Medical Device Class 1 Approved by KFDA + Item List

Product Code : A64050.01 Class 1 Purpose : Clinical guide Product Name : Anatdel

- 01\_ BCS-001 Brain cancer surgery guide
- 02\_ ICVD-001 Interventional coronary vascular disease therapy guide
- 03\_ NDS-001 Nerovascular disease surgery guide
- 04\_ IND-001 Interventional Neurovascular disease therapy guide
- 05\_ IAA-001 Interventional aortic aneurysm therapy guide
- 06\_ LS-001 Laparoscopic surgery guide
- 07\_ PCSS-001 Pediatric congenital skull surgery guide
- 08\_ PCHS-BH-001 Pediatric congenital heart surgery guide
- 09\_ PCHS-HL-001 Pediatric congenital heart surgery guide
- 10\_ PACS-001 Pediatric abdominal cancer surgery guide
- 11\_ IMR-001 Interventional Mitral Regurgitation (MR) disease therapy guide
- 12\_ KSPN-001 Kidney stone Percutaneous Nephrolithotomy guide
- 13\_ KSRIS-001 Kidney stone Retrograde IntraRenal surgery guide
- 14\_ RCCPNS-001 Renal Cell Carcinoma partial nephrectomy surgery guide
- 15\_ LCLS-001 Lung cancer Lobectomy surgery guide

# **References**

# **Lists of Published Journal Papers**

Chul-Kee Park **3D-Printed Disease Models for Neurosurgical Planning, Simulation, and Training**  *J Karean Neurosurg Soc* . 2022 Jul;65(4):489-498. doi: 10.3340/jkns.2021.0235. Epub 2022 Jun 28.

Young Hyo Choi 1, Seung-Ju Lee 1, Hee Youn Kim 2 Effect of a three-dimensional (3D) printed kidney model on patient understanding of the percutaneous nephrolithotomy procedure: a preliminary study Urolithiasis

. 2022 Jun;50(3):375-380. doi: 10.1007/s00240-022-01308-3. Epub 2022 Feb 5.

Jin Woo Bae 1, Da Yeong Lee 2, Chang Hwan Pang 1, Jeong Eun Kim 1, Chul-Kee Park 1, Doohee Lee 2, Sang Joon Park 3, Won-Sang Cho 4 **Clinical application of 3D virtual and printed models for cerebrovascular diseases** *Clin Neurol Neurosurg* . 2021 Jul;206:106719. doi: 10.1016/j.clineuro.2021.106719. Epub 2021 May 29..

Cheul Lee 1, Jae Young Lee 2 **Utility of three-dimensional printed heart models for education on complex congenital heart diseases**  *Cardiol Young* . 2020 Nov;30(11):1637-1642. doi: 10.1017/S1047951120003753. Epub 2020 Nov 9.

Jung Kwon Kim 1, Hoyoung Ryu 2, Myong Kim 3, Eun-Kyung Kwon 1, Hakmin Lee 1, Sang Joon Park 4, Seok-Soo Byun 1 5 **Personalised three-dimensional printed transparent kidney model for robot-assisted partial nephrectomy in patients with complex renal tumours (R.E.N.A.L. nephrometry score**  $\geq$ **7**): a prospective case-matched study *BJU Int* 

. 2021 May;127(5):567-574. doi: 10.1111/bju.15275. Epub 2020 Nov 4.

## Hyun Woo Goo, MD, PhD,1 Sang Joon Park, PhD,2 and Shi-Joon Yoo, MD3 Advanced Medical Use of Three-Dimensional Imaging in Congenital Heart Disease: Augmented Reality, Mixed Reality, Virtual Reality, and Three-Dimensional Printing

Korean J Radiol. 2020 Feb;21(2):133-145. English. Published online Jan 08, 2020. https://doi.org/10.3348/kjr.2019.0625

Ijin Joo 1, Jung Hoon Kim 1 2, Sang Joon Park, Kyoungbun Lee 3, Nam-Joon Yi 4, Joon Koo Han 1 2 Personalized 3D-Printed Transparent Liver Model Using the Hepatobiliary Phase MRI: Usefulness in the Lesion-by-Lesion Imaging-Pathologic Matching of Focal Liver Lesions-Preliminary Results Invest Radiol

. 2019 Mar;54(3):138-145. doi: 10.1097/RLI.0000000000000521.

Soon Ho Yoon 1, Samina Park 2, Chang Hyun Kang 2, In Kyu Park 2, Jin Mo Goo 3, Young Tae Kim 4 **Personalized 3D-Printed Model for Informed Consent for Stage I Lung Cancer: A Randomized Pilot Trial** Semin Thorac Cardiovasc Surg. 2019;31(2):316-318. doi: 10.1053/j.semtcvs.2018.10.017. Epub 2018 Nov 7..

Soon Ho Yoon 1, Jin Mo Goo 1 2, Chang-Hoon Lee 3, Jae Young Cho 3, Dong-Wan Kim 3, Hak Jae Kim 4, Jin Cheol Paeng 5, Young Tae Kim 6 Virtual reality-assisted localization and three-dimensional printing-enhanced multidisciplinary decision to

treat radiologically occult superficial endobronchial lung cancer Thorac Cancer . 2018 Nov;9(11):1525-1527. doi: 10.1111/1759-7714.12879. Epub 2018 Sep 25.

Dong Hoon Lee 1, Tae Mi Yoon, Joon Kyoo Lee, Sang Chul Lim **The role of 3D-printing technology in the diagnosis of Eagle syndrome: A case report**  *Medicine (Baltimore)* . 2018 Mar;97(13):e9989. doi: 10.1097/MD.000000000009989.



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