

[Information on environmental effects]

Decomposability No information available
Eco toxicity No information available

[Notes for disposing the lubricant]

Use up the lubricant before disposing of the container.
Do not throw the container into a fire even after the lubricant is used up, as the container may explode.
If the container is disposed, press the push button in a fire-free outdoor area and spray the lubricant at an unwanted article such as old newspapers to completely remove the lubricant from the container. (After spraying the lubricant, ensure that there is no spraying noise.)
Do not puncture a hole in the container unless a directive has been issued by the local government. When puncturing a hole in the container, use a commercially available punch press while being careful about any of the lubricant.
Request an industrial waste disposal professional licensed by the local government to dispose of the container and the lubricant contained. Properly dispose of industrial waste according to relevant laws and regulations.

[Notes for transportation]

Follow the general precautions in Item Notes for handling and Notes for storage. When transporting the lubricant in a container, keep the container at 40°C or less. In addition, load lubricant containers in such a way as to avoid direct sunlight, falls, drops, and damage to the container and take proper measures to prevent the collapse of cargo piles.
UN number: 1950 (Aerosol)

[Applicable laws and regulations]

Fire Defense Law	Article 2 Hazardous material, Classification 4, First oils
Material with its notification required under the Occupational Health and Safety Law	First hazardous materials, separate sheet, Case of enforcement (inflammables and combustibles) 62 Ethanol, separate sheet, the 9th case of enforcement (Materials with concentration of 1%) 480, butane, separate sheet, the 9th case of enforcement
Danger regulations	Article 3, hazardous materials notification, separate sheet, the 5th inflammable liquid liquids, the 2nd high pressure gas
Aviation Law	Article 194, applicable rules, hazardous materials notification, separate sheet, the 3rd inflammable liquids, the 2nd high pressure gas
Harbor regulations	Article 12, applicable rules, hazardous material (inflammable liquids, high pressure gas)
Law Concerning the Promotion of Understanding and Management of Emissions into the Environment of Specific Chemical Substances	Not compliant
High Pressure Gas Safety Law	Not applicable (Aerosol)

[References]

12093 Chemical Commodities (the Chemical Daily)
New Solvent Pocket Book (The Society of Synthetic Organic Chemistry, Japan)
Material Maker Product Safety Data Sheet
Guidelines for product safety data sheet preparation (Nippon Chemical Industrial Co., Ltd.)

Precautions

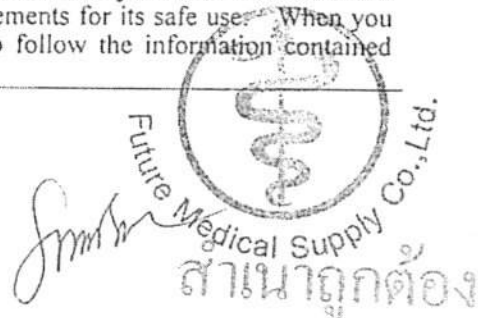
This product safety data sheet has been prepared based on the most accurate and reliable references, information, and data currently available as reference information for ensuring safe use and handling. However, much of the information contained has been obtained outside the company. Therefore, the accuracy and reliability of the information contained cannot be guaranteed. Nor is any warranty of these products indicated made.

Notes contained herein concerning health and safety do not cover all effects on people, the environment, and health. Because all materials can contain unknown risks or harmfulness, great care must be exercised in handling the lubricant.

When using the lubricant, you are asked to follow related laws and regulations under your own discretion and responsibility with reference to the product safety data sheet and to set requirements for its safe use. When you have obtained the latest information on the lubricant, you are also asked to follow the information contained therein and use the lubricant safely.



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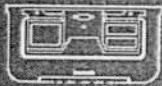


STANDARD PLUS

STERILE CONTAINER SYSTEMS

1/2 Half Size

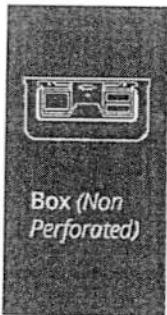
Box Types



Box (Perforated)



Box (Non Perforated)



Code	Outside Dimension	Inside Dimension	Weight
3.25. K6-605	310 x 272 x 96 mm	253 x 258 x 90 mm	1285 g
K6-606	310 x 272 x 116 mm	253 x 258 x 110 mm	1345 g
K6-607	310 x 272 x 138 mm	253 x 258 x 132 mm	1455 g
K6-608	310 x 272 x 185 mm	253 x 258 x 179 mm	1705 g
K6-609	310 x 272 x 235 mm	253 x 258 x 229 mm	1955 g



Code	Outside Dimension	Inside Dimension	Weight
K6-600	310 x 272 x 96 mm	253 x 258 x 78 mm	1400 g
K6-601	310 x 272 x 116 mm	253 x 258 x 99 mm	1460 g
K6-602	310 x 272 x 138 mm	253 x 258 x 121 mm	1570 g
K6-603	310 x 272 x 185 mm	253 x 258 x 167 mm	1820 g
K6-604	310 x 272 x 235 mm	253 x 258 x 218 mm	2070 g



LID & BASE SPECS

In Sterilization Containers

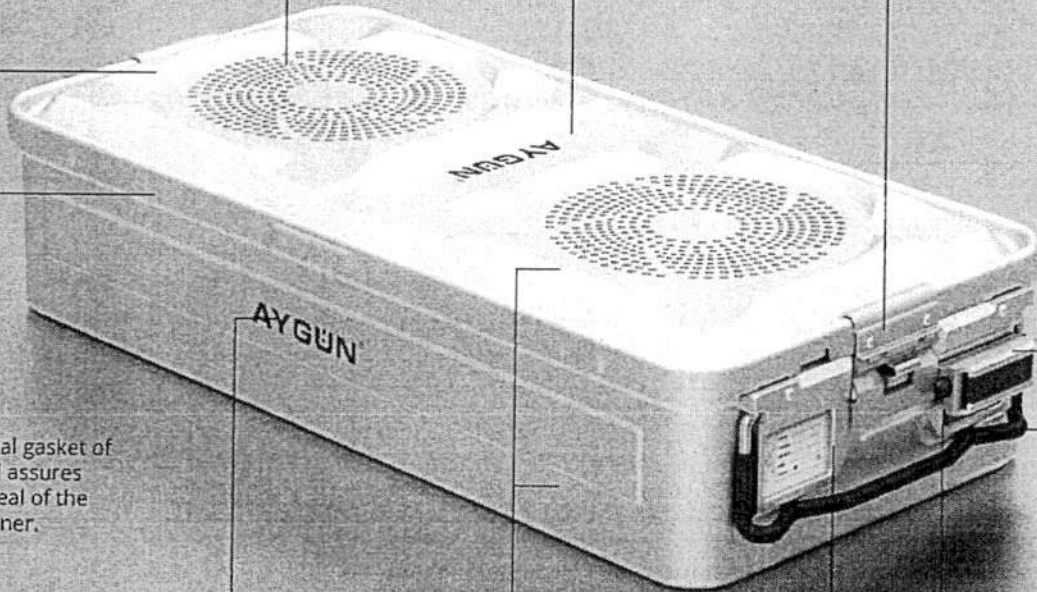
Special lid design for stackability!

Sealed filter retainers having 2 springs inside and pre-tensioning feature enable fast, easy and secure change of the filters by seating solidly on the surface.

Optional OEM marking possibility!

Locking mechanism ensures better grip with its flexible design structure including 2 springs inside and performing "single-step" movement.

Heat sensitive modular auto lock mechanism offers safer result for sterilization process.



Internal gasket of the lid assures safe seal of the container.

Wide, special design, silicone coated handles let easy and safe handling of the container and avoids hand injuries. 8 different colors available.

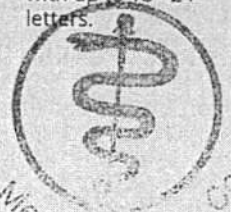
Optional OEM marking possibility!

Corrosion resistant lid and bottom made of 2 mm high quality special alloy aluminium!

Face plates on both sides of the container are made of one single piece!

Identification labels can be marked with up to 18 - 24 letters.

AYGUN
SURGICAL INSTRUMENTS CO., INC.



สำนักงานถูกต้อง

3.25 - 3.26
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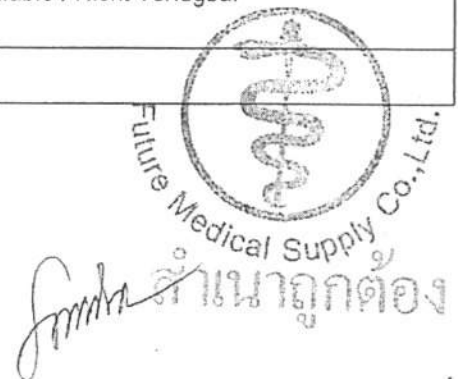
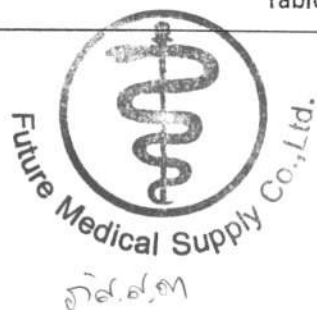
Yüzey : Eloksallı	Surface : Anodized	Oberfläche: Eloxiert
Renk: Gri	Color: Grey	Farbe: Grau
Delik Tipi:	Hole Type:	Lochtyp:
A- Standart / Standart Plus Filtre Mekanizması B- Biyo Bariyer Valf Sistemi C- B3 PTFE Filtre Mekanizması D-B3 Valf Mekanizması E- B3 Bio-Stop Sistem	A-Standard / Standard Plus Filter Mechanism B-Bio-Barrier Valve System C-B3 PTFE Filter Mechanism D-B3 Valve Mechanism E-B3 Bio-Stop System	A-Standard / Standart Plus Filtermechanismus B-Bio-Absperrventil- System C-B3 PTFE Filtermechanismus D-B3 Ventilmechanismus E-B3 Bio-Stopp-System

Boyut / Sizes/Größe:	Mekanizma / Mechanism/ Mechanismus				
	A	B	C	D	E
1/1 Full Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
3/4 Quarter Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
1/2 Half Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Extra Large Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Extra Long Size	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Large Dental	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Dental Size	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1/2 Dental Size	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mini Size	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flat Size	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Endo Size	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Implant & Mini Implant ¹	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Scopy Size ¹	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

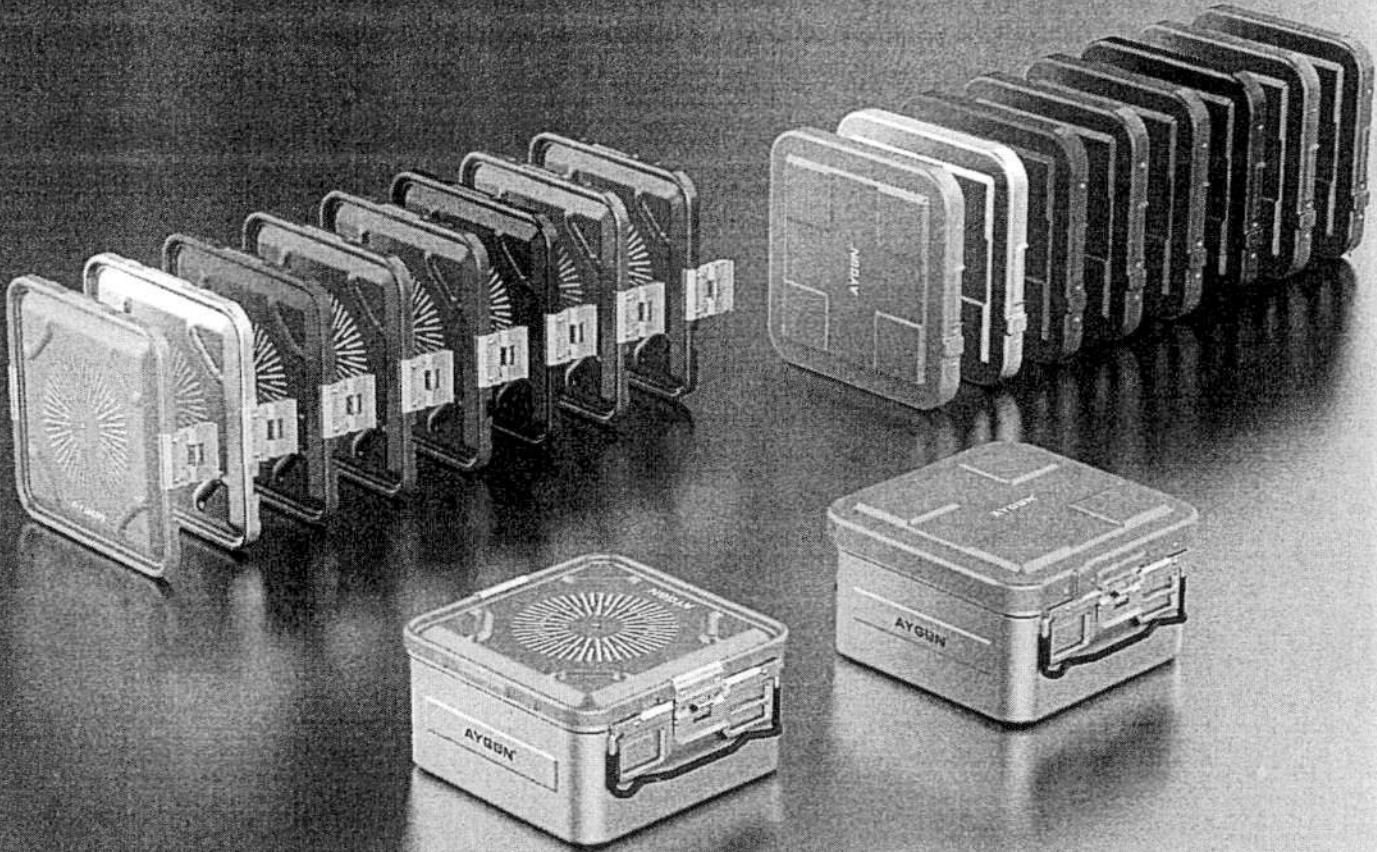
¹ Sadece taşıma amaçlı konteynerlerdir. Sterilizasyona uygun konteynerler içerisinde düzenleyici olarak kullanılabilir.	¹ Used only for transport purposes. They can be used organizer in containers suitable for sterilization.	¹ Wird nur für Transportzwecke verwendet. Diese können als Organisator in Containern verwendet werden, die zur Sterilisation geeignet sind.
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Mevcut / Available / Verfügbar Mevcut Değil /Not Available / Nicht Verfügbar

Tablo / Table / Tabelle -1



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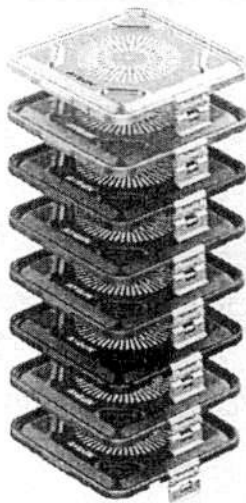


8 Different Colours

Perforated Lids

Dimension
295 x 280 mm

Weight
765 g

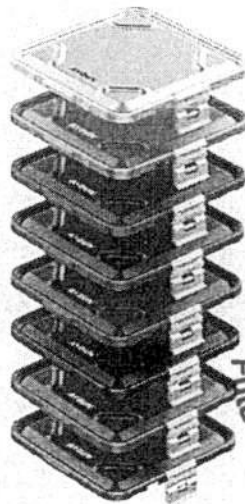


Color	Code
Grey	3.26. K6-630
Yellow	K6-631
Green	K6-632
Blue	K6-633
Red	K6-634
Black	K6-635
Purple	K6-636
Bronze	K6-637

Removal Lids

Dimension
295 x 280 mm

Weight
640 g

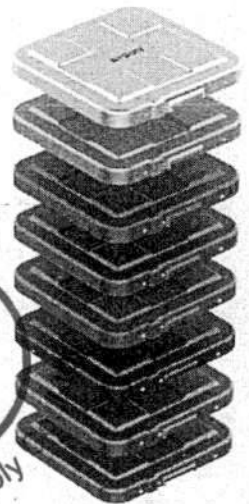


Color	Code
Grey	K6-620
Yellow	K6-621
Green	K6-622
Blue	K6-623
Red	K6-624
Black	K6-625
Purple	K6-626
Bronze	K6-627

Safety Lids

Dimension
317 x 285 mm

Weight
620 g



Color	Code
Grey	K6-700
Yellow	K6-701
Green	K6-702
Blue	K6-703
Red	K6-704
Black	K6-705
Purple	K6-706
Bronze	K6-707



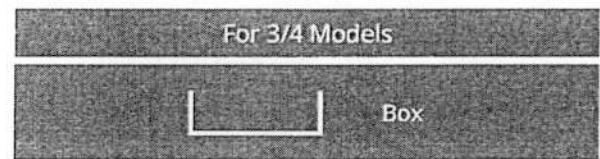
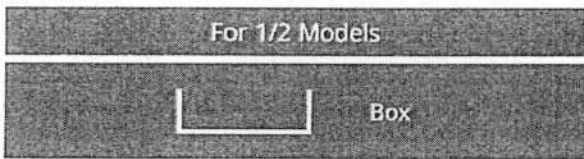
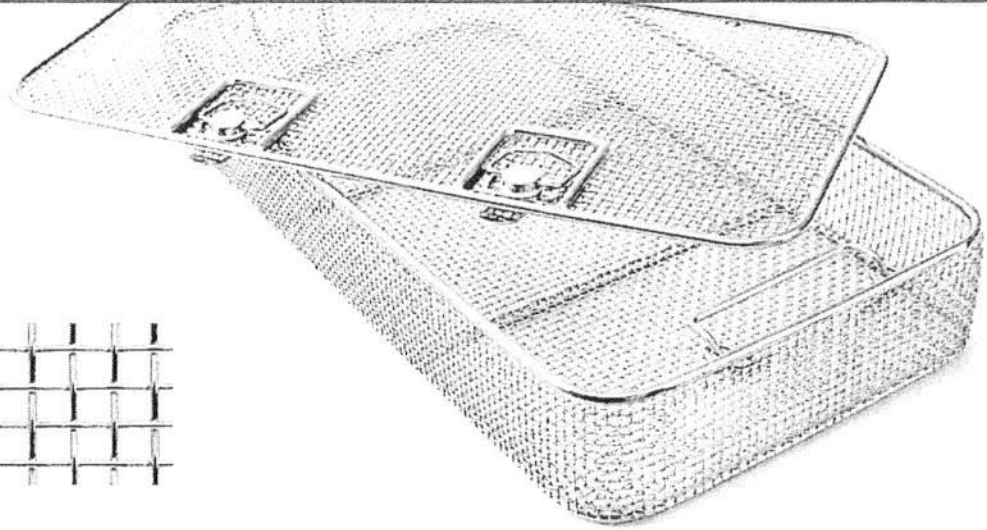
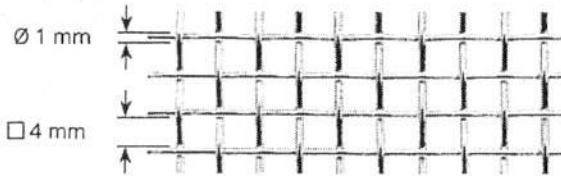
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▽ BASKET MADE FROM STAINLESS STEEL WIRE MESH

BASKETS
STERILE CONTAINER SYSTEMS

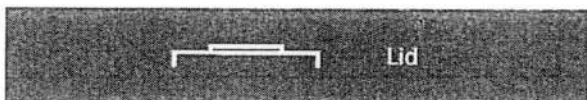
Mesh grid

Actual Size

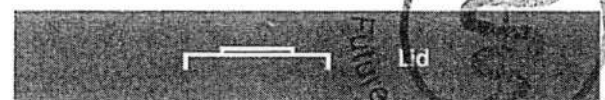


Code	Outside Dimension
K2-490	246 x 246 x 30 mm
K2-491	246 x 246 x 50 mm
3.27. K2-492	246 x 246 x 70 mm
K2-493	246 x 246 x 100 mm

Code	Outside Dimension
K2-1500	405 x 245 x 30 mm
K2-1501	405 x 245 x 50 mm
K2-1502	405 x 245 x 70 mm
K2-1503	405 x 245 x 100 mm



Code	Outside Dimension
K3-1045	246 x 246 mm



Code	Outside Dimension
K3-1034	405 x 245 mm

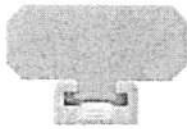
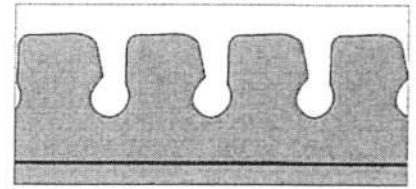
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Instruments holder, Ø 5 mm
With rail, screw and nut

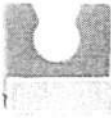
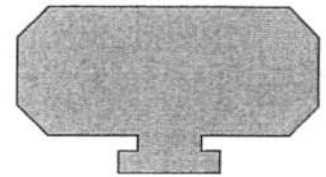
Code	Lenght	Height
K12-125	178 mm	24 mm

Actual Size



Code	Lenght	Height
K12-142	40 mm	25 mm

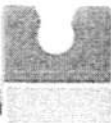
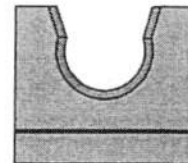
Actual Size



Code	Lenght	Height
K12-126	23.5 mm	25 mm

Ø 10,5 mm With rail, screw and nut

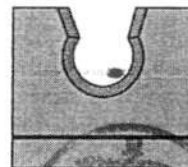
Actual Size



Code	Lenght	Height
K12-127	23.5 mm	25 mm

Ø 8 mm With rail, screw and nut

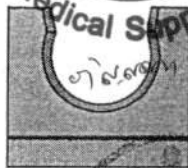
Actual Size



Code	Lenght	Height
3.28. K12-128	23.5 mm	25 mm

Ø 13 mm With rail, screw and nut

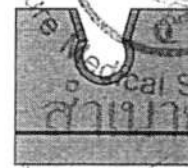
Actual Size



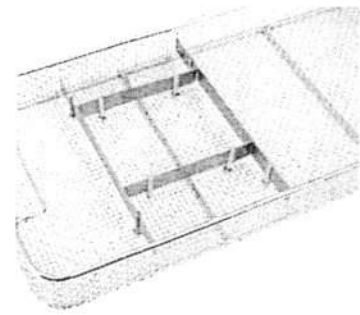
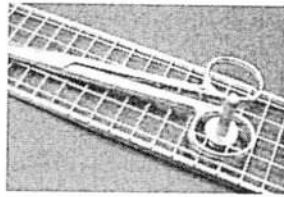
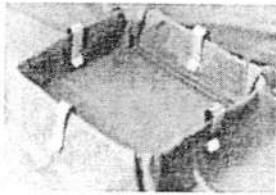
Code	Lenght	Height
K12-129	23.5 mm	25 mm

Ø 5 mm With rail, screw and nut

Actual Size



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 Actual Size
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K2-650

Holding pin for divider



K2-651

Holding pin for instruments



K2-588

Fixation clamp

K2-645

DIVIDER
50 x 20 mm

K2-646

DIVIDER
130 x 20 mm

K2-647

DIVIDER
225 x 20 mm

K2-648

DIVIDER
460 x 20 mm

HOLDERS & DIVIDERS



K2-580
Ø 7 - 12 mm



K2-581
Ø 12 - 16 mm



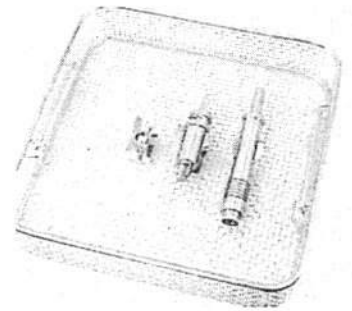
3.29.
K2-582
Ø 16 - 26 mm



K2-583
Ø 26 - 36 mm

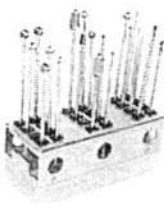


K2-584
Ø 36 - 45 mm



Code Outside Dimension
K8-508 98 x 43 x 44 mm

Rack for 24 burrs with shanks
Ø 2.35 mm



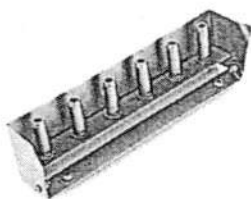
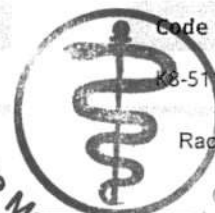
Code Outside Dimension
K8-509 163 x 103 x 40 mm

Rack for 15 pcs of instruments



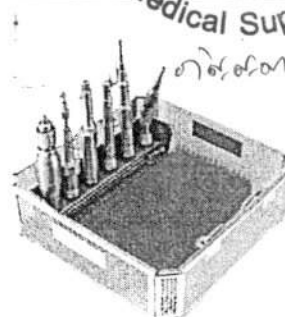
Code Outside Dimension
K8-511 218 x 22 x 54 mm

Rack for 12 pcs of instruments

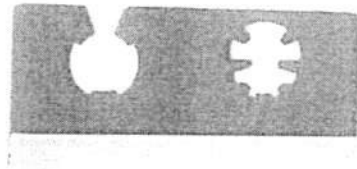


Code Outside Dimension
K8-190 218 x 45 x 52 mm

Tiltable holding device
for 6 micro heads

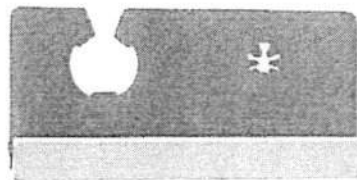
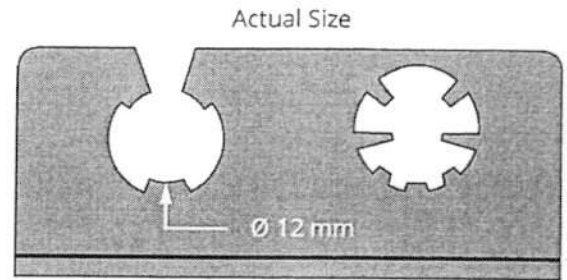


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ตัวแทนลูกค้าต้อง



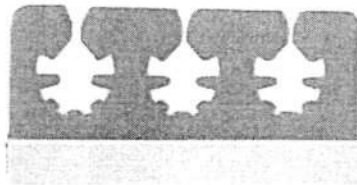
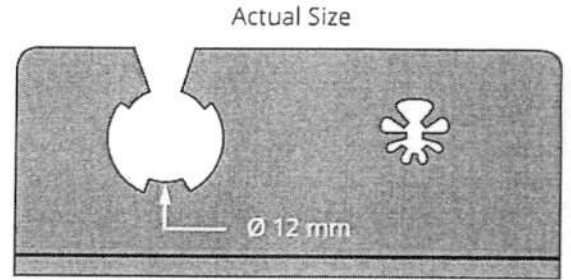
Code	Length	Height
K12-130	72 mm	34 mm

Endoscope holder, double
 One side \varnothing 12 mm open
 One side from \varnothing 3 to \varnothing 15 mm closed With rail, screw and nut



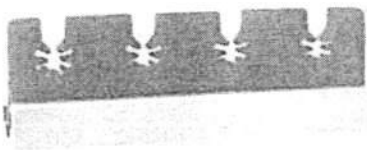
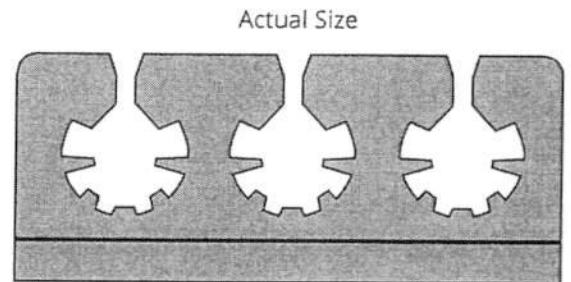
Code	Length	Height
K12-141	72 mm	34 mm

Endoscope holder, double
 One side \varnothing 12 mm open
 One side from \varnothing 3 to \varnothing 8 mm closed With rail, screw and nut



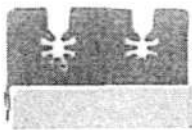
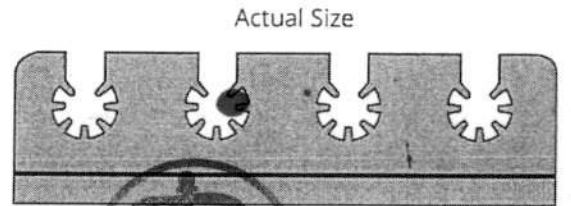
Code	Length	Height
3.30. K12-131	72 mm	34 mm

Instruments holder from \varnothing 3 to \varnothing 15 mm With rail, screw and nut



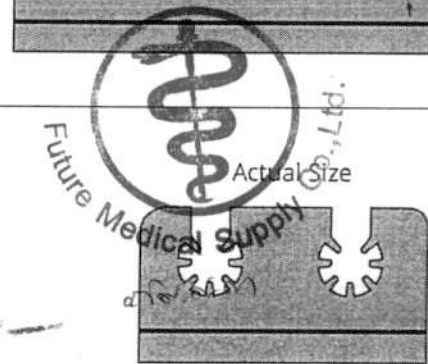
Code	Length	Height
K12-132	72 mm	24 mm

Instruments holder, from \varnothing 3 to \varnothing 8 mm With rail, screw and nut



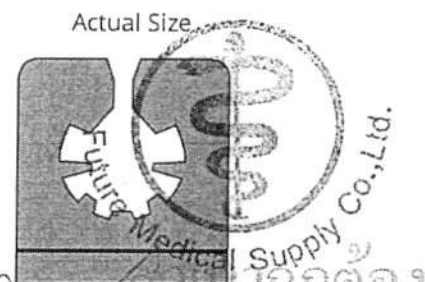
Code	Length	Height
K12-133	38 mm	24 mm

Endoscope holder, double one side from \varnothing 3 to \varnothing 8 mm With rail, screw and nut



Code	Length	Height
K12-134	28 mm	34 mm

Endoscope holder, single one side \varnothing 12 mm open one side from \varnothing 3 to \varnothing 15 mm With rail, screw and nut



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 011 663 0000



TROL-06 3.31.

รถเข็นสเตนเลส 2 ชั้น 1 ลิ้นชัก

ขนาด กว้าง 50 x ลึก 40 ซม. X สูง 80 ซม.

มีมือจับ มีก้นตัก 3 ด้าน มีที่พันสายไฟ มี 4 ล้อ ล้อมีเบรค 2 ล้อ



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SYNDROME

ผู้นำด้านระบบสำรองไฟฟ้า
เครื่องควบคุมและสำรองไฟฟ้า (UPS)
Uninterruptible Power Supply
Line Interactive with Stabilizer

คลาสสิก สำหรับอุปกรณ์คุณภาพสูง

Innovative
UPS
SYNDROME

SZ-Pro Series



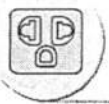
มี LED แสดงระดับการใช้งานของ Battery และ อุปกรณ์ต่อพ่วง



มีระบบป้องกันไฟกระชากทางสายโทรศัพท์ (Surge Protection)



มีถาด Hot Swap ทำให้สามารถเปลี่ยน Battery อย่างง่ายด้วยมือเปล่า



ได้รับแบบ Universal รับปลั๊กเสียบได้ทั้งขากลมและขาแบน



ควบคุมการทำงานของ UPS ด้วย Software อัจฉริยะ



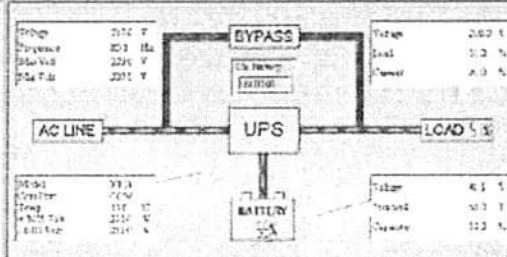
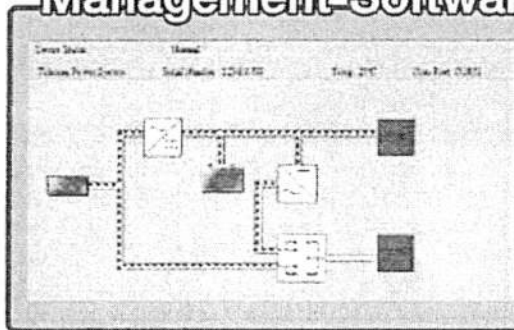
เชื่อมต่อคอมพิวเตอร์ด้วย USB/RS232 Port

Product Features

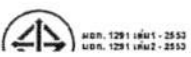
- เครื่องสำรองไฟฟ้าชนิด Line Interactive with Stabilizer
- ควบคุมการทำงานด้วยไมโครโปรเซสเซอร์สมบูรณ์แบบ
- ปรับแรงดันไฟฟ้าได้โดยอัตโนมัติ สามารถใช้งานได้ทั่วประเทศ
- ซอฟต์แวร์อัจฉริยะที่ทำงานร่วมกับ UPS เพื่อดูแล Computer
- สามารถเปิดเครื่องโดยใช้ไฟจากแบตเตอรี่
- ผู้ใช้สามารถเปลี่ยนแบตเตอรี่ได้เองอย่างง่ายดายโดยไม่ต้องปิดเครื่อง (ในสภาวะปกติ)
- มี Switch ทดสอบแบตเตอรี่ และตัดสัญญาณเสียงเตือน
- ตรวจสอบสภาพแบตเตอรี่เองโดยอัตโนมัติ
- มีอุปกรณ์ป้องกันไฟกระชากและสัญญาณรบกวน
- ระบบป้องกันไฟกระชากในสายโทรศัพท์
- ระบบปิดเครื่องอัตโนมัติ เมื่อไม่มีการใช้งาน (option)
- แสดงระดับการใช้กระแสไฟฟ้าของอุปกรณ์ต่อพ่วง
- แสดงระดับการใช้งาน และการประจุของแบตเตอรี่



Management Software



- Power flow display for monitoring UPS status
- Scheduled system shutdown / restart
- Scheduled UPS test
- Warning notification e-mail / sms
- Password security protection
- Remote monitor / control via LAN/WAN/INTERNET
- Safety to shutdown multi-system
- Selectable UI Interface (Backlight)
- UPS parameter setting
- Record logs for analysis
- Auto check UPS connection via USB / RS-232 / LAN
- Support operating system: Windows XP/7/10, Vista, Linux, Linux AMD64, Sun Solaris 7/8/9, IBM AIX 4.3 and 5.1, HP-UX 11.x, FreeBSD, Unix, Altix System (not for Intel 32bit), MAC version

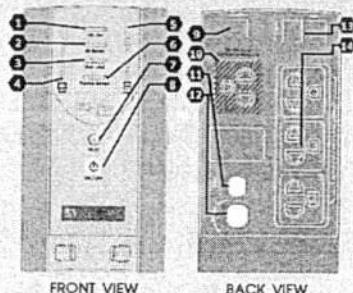


Syndrome Electronics Industry Co., Ltd.
66 ซอยประชาอุทิศ 59 แขวง 3 แขวงบางนา เขตทุ่งครุ กรุงเทพฯ 101.
Tel: (662) 8726900 (multi) Fax: (662) 8726901

Specification

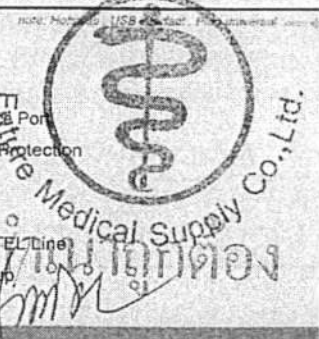
SZ-Pro
Series

Model		UPS500	UPS800	UPS1000	UPS1200	UPS1500
Input	ภาคไฟฟ้าขาเข้า	3.32				
Voltage	แรงดันไฟฟ้า	220 VAC ± 25%				
Frequency	ความถี่ไฟฟ้า	50 Hz ± 10%				
Output	ภาคไฟฟ้าขาออก					
Power Rating	ขนาดกำลังจ่าย	500VA/400W	800VA/640W	1KVA/800W	1.2KVA/960W	1.5KVA/1200W
Voltage Stabilizer	แรงดันไฟฟ้าในโหมดปรับแรงดัน	220 VAC ± 10%				
Voltage Backup	แรงดันไฟฟ้าในโหมดจ่ายไฟสำรอง	220 VAC ± 5%				
Frequency	ความถี่ไฟฟ้า	50 Hz ± 0.1%				
Wave Form	รูปแบบของคลื่นสัญญาณไฟฟ้า	Simulated sine wave				
System & Protection	ระบบ และ การป้องกัน					
System	ระบบการทำงาน	on-line protection / line interactive				
Over Voltage	ระบบป้องกันไฟฟ้าเกินกว่าปกติ	power line to back up 220 VAC + 25%				
Under Voltage	ระบบป้องกันไฟฟ้าต่ำกว่าปกติ	power line to back up 220 VAC - 25%				
Transfer Time	ระยะเวลาในการโอนย้ายแหล่งจ่ายไฟฟ้า	less than 2 ms (Typical)				
Battery	แบตเตอรี่	sealed lead acid maintenance free				
Back Up Time	ระยะเวลาในการสำรองไฟ	20-30 minutes (depends on load)				
Charger	การประจุแบตเตอรี่	constant voltage and current limit				
Recharge Time	ระยะเวลาในการประจุแบตเตอรี่	4-6 hours (90% after fully discharged)				
Output Protection	การป้องกันไฟฟ้าขาออก	short circuit protected , Overload protection				
Overload Protection	การป้องกันการใช้งานเกินกำลัง	Fuse protection on line mode & UPS cut-off on back up mode				
Battery Protection	การป้องกันแบตเตอรี่	Overcharge protection & Low battery cut-off				
Operating Temperature	อุณหภูมิ	0 - 40°C				
Operating Humidity	ความชื้นสัมพัทธ์	0 - 95%				
Audible Noise	ความดังของเสียงขณะเครื่องทำงาน	less than 30dB (at one meter)				
Smart Features & Indicators	คุณสมบัติเด่น และการแสดงผล					
Intelligent Interface	การเชื่อมต่อกับคอมพิวเตอร์	USB				RS 232
Tel. Line Protection	ป้องกันไฟกระชากทางแลนสายโทรศัพท์	Yes				
Test Switch / Alarm Mute	ปุ่มทดสอบการทำงานของเครื่อง / หยุดเสียงเตือน	Yes				
Automatic No Load Shutdown	ปิดเครื่องอัตโนมัติเมื่อไม่ได้ใช้งานโหลด	Yes				
Alarm	สัญญาณเตือน	AC fail alarm ,Overload alarm ,Battery low alarm ,UPS fault alarm Continuous				
Indicator	ไฟแสดงผล	AC/On line mode Green LED, UPS Back up/On battery Red LED				
Load Level	ไฟแสดงระดับการใช้งานอุปกรณ์ต่อพ่วง	Yes				
Batt Level	ไฟแสดงระดับแบตเตอรี่	Yes				
Replace Battery	ไฟแสดงสถานะเมื่อต้องเปลี่ยนแบตเตอรี่	Yes				
Dimensions	มิติของเครื่อง					
Size (w x d x h) (cm)	ขนาด (กว้าง x ยาว x สูง)(เซนติเมตร)	9.7 x 29.7 x 17.8	12 x 36 x 20	12 x 36 x 20	12 x 40 x 20	12 x 40 x 20
Weight (kg)	น้ำหนัก (กิโลกรัม)	6.2	6.9	15	20	21
Product standard	มาตรฐานผลิตภัณฑ์	TIS 1291 Part 1-2553 , TIS 1291 Part 2-2553 , TIS 1291 Part 3-2555 Class C1				
QMS	ระบบบริหารงานคุณภาพ	Certified Quality Management System ISO9001				
EMS	ระบบบริหารสิ่งแวดล้อม	Certified Environmental Management System ISO14001				



INDICATOR

1. On Line
2. On Battery
3. Over Load
4. Battery Level
5. Load Level
6. Replace Battery
7. Test / Alarm Mute Switch
8. Power ON / OFF
9. USB/RS 232 Interface Port
10. Output for Printer Protection
11. Input Fuse
12. Input Cable Cord
13. Surge Protection TEL Line
14. Output UPS Backup





บัตรประจำตัวประชาชน Thai National ID Card
 เลขประจำตัวประชาชน Identification Number 3 1305 00068 30 9

ชื่อตัวและชื่อสกุล นาย สมนึก วงษ์สงัด
 Name Mr. Somnuek Wongsamng

Last name Wongsamng

เกิดวันที่ 12 เม.ย. 2514
 Date of Birth 12 Apr. 1971

ศาสนา พุทธ

ที่อยู่ 229/6 ซอยคณาธิเบศร์ 28 ต.บางกระสอ

บ.เมืองนนทบุรี จ.นนทบุรี

3 มี.ค. 2564

3 มี.ค. 2021

Date of Issue

11 เม.ย. 2572

11 Apr. 2029

Date of Expiry



1299-06-03031337



สำเนาถูกต้อง

[Handwritten signature]



๑๖๘,๗.๓๓

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

FUTURE MEDICAL SUPPLY CO., LTD.
18 S.Liang Mueang Nonthaburi 4,
T.Talat kwan, A.Mueang Nonthaburi,
Nonthaburi
11000
Thailand

Holds Certificate Number:

MD 682381

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The distribution of surgical devices, surgical tools and instruments including maintenance products.

The distribution of sterilization containers and sterilization accessories including maintenance products.

The distribution of radiation protective clothes and accessories.



Gary E Slack (Handwritten signature)

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-02-15

Effective Date: 2021-02-15

Latest Revision Date: 2021-01-28

Expiry Date: 2024-02-14



Page: 1 of 1

...making excellence a habit.



This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](https://www.bsi-global.com/ClientDirectory).

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +66(2) 2944889-92.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 & EN ISO 13485:2016 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.

Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2002410-1

Organization: Nakanishi Inc.
700 Shimohinata,
Kanuma, Tochigi,
322-8666 Japan

Scope: Design and Development, Manufacture, Distribution and Service of
Instruments and Equipment in Dental and Surgical Field.
(see attachments for products and additional sites included)



The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150268114-301
Effective date: 2023-04-27
Expiry date: 2026-04-26
Issue date: 2023-04-24



Atsushi Kato
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



Signature 117

Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2002410-1

Organization: Nakanishi Inc.
700 Shimohinata,
Kanuma, Tochigi,
322-8666 Japan

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Nakanishi Inc. 700 Shimohinata, Kanuma, Tochigi, 322-8666 Japan	Design, Development, Manufacture and Distribution of Pneumatic dental drilling system handpiece Diamond dental bur, reusable Dental drilling system attachment Line-powered dental drilling system handpiece Pneumatic dental scaling system handpiece Pneumatic dental scaling system handpiece tip Air Motor Remotely-driven dental drilling system motor Endodontic enlarger Dental-professional prophylaxis motor Endodontic apex locator Dental abrasive air jet system handpiece Dental abrasive powder Sawing power tool attachment, reciprocating Sawing power tool attachment, oscillating Sawing power tool attachment, sagittal Reciprocating surgical saw blade, reusable Oscillating surgical saw blade, reusable Sagittal surgical saw blade, reusable Dental implant system



Report No.: 150268114-301
Effective date: 2023-04-27
Expiry date: 2026-04-26
Issue date: 2023-04-24



Atsushi Kato
TUV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Signature 217