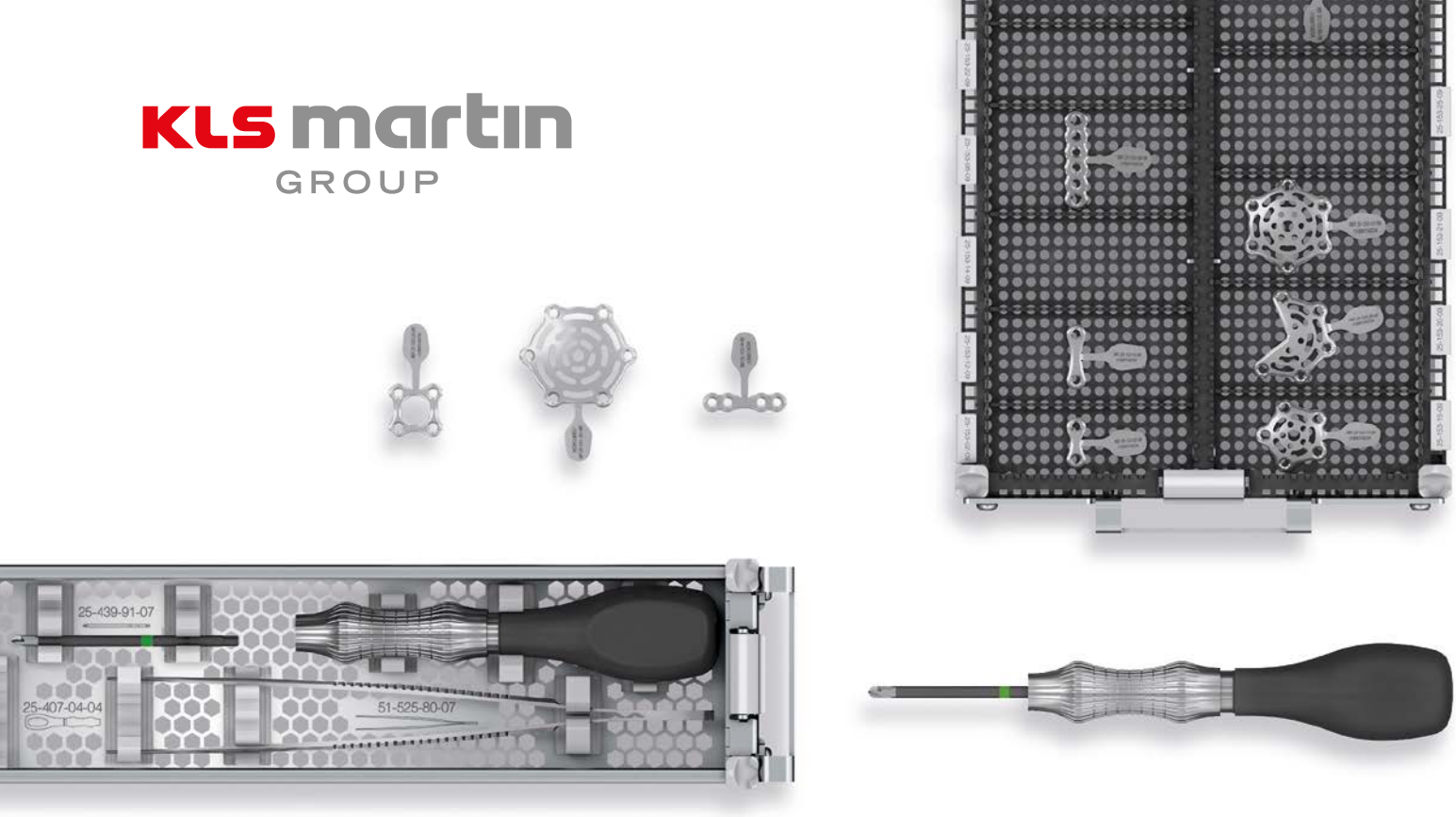
KLS martin GROUP



L1® Cranium

Neuro Osteosynthesis

www.klsmartin.com

Oral and maxillofacial surgery is our passion! Its further development, together with our customers, is our ambition. Every day we work on developing innovative products and services which meet the highest demands on quality, and which contribute to the wellbeing of the patient.

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Standard
KLS martin
KLS martin

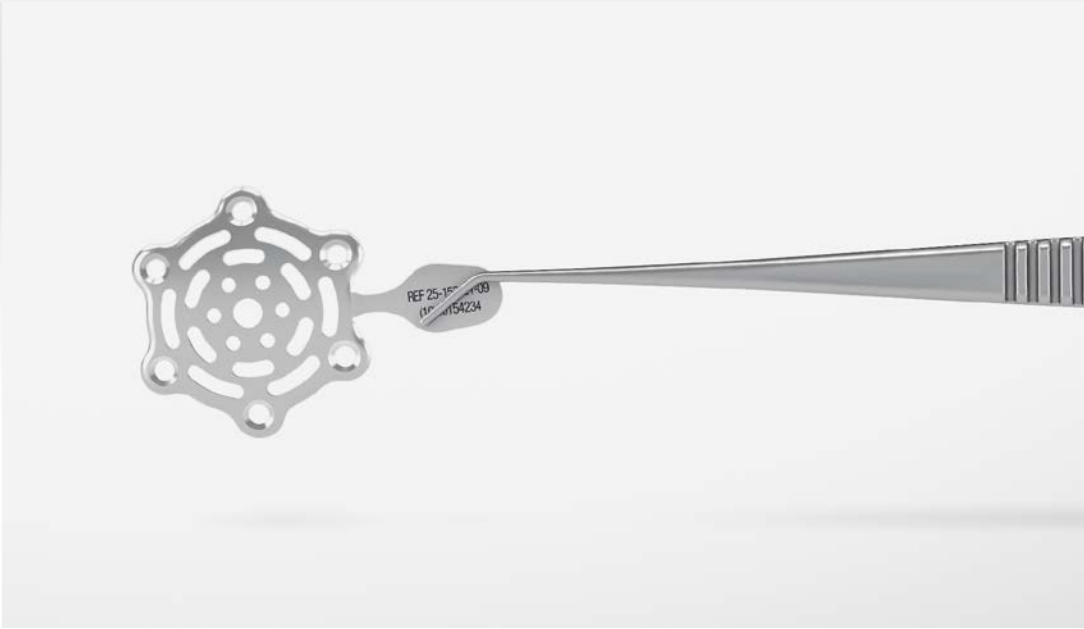
L1® Cranium –
Osteosynthesis of the skullcap

The skullcap is of decisive importance in terms of function and esthetics. It defines the outer appearance by giving the skull its characteristic roundness. In addition, its protective function is essential for the brain.

High impact traumatic events can result in fractures leading to a loss of bony integrity. Other circumstances such as tumors, growth disorders, or an increase in intracranial pressure may also necessitate a craniotomy.

Regardless of the cause, bone fragments and cranial flaps must be reduced and fixated osteosynthetically. The L1® Cranium System was developed to restore the function and esthetics of the skullcap.

Feature, Function and Benefit

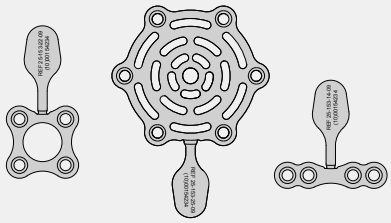
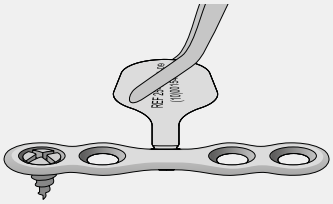
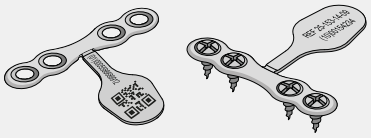
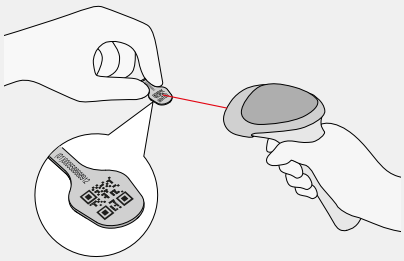
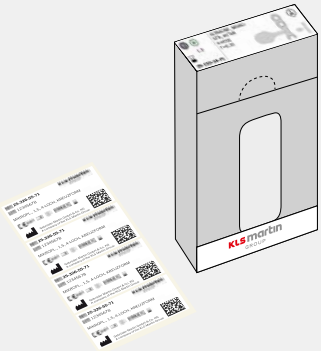


With its wide range of ultraOne plates, the L1® Cranium System is ideally suited to treat a wide variety of indications in the region of the skullcap.

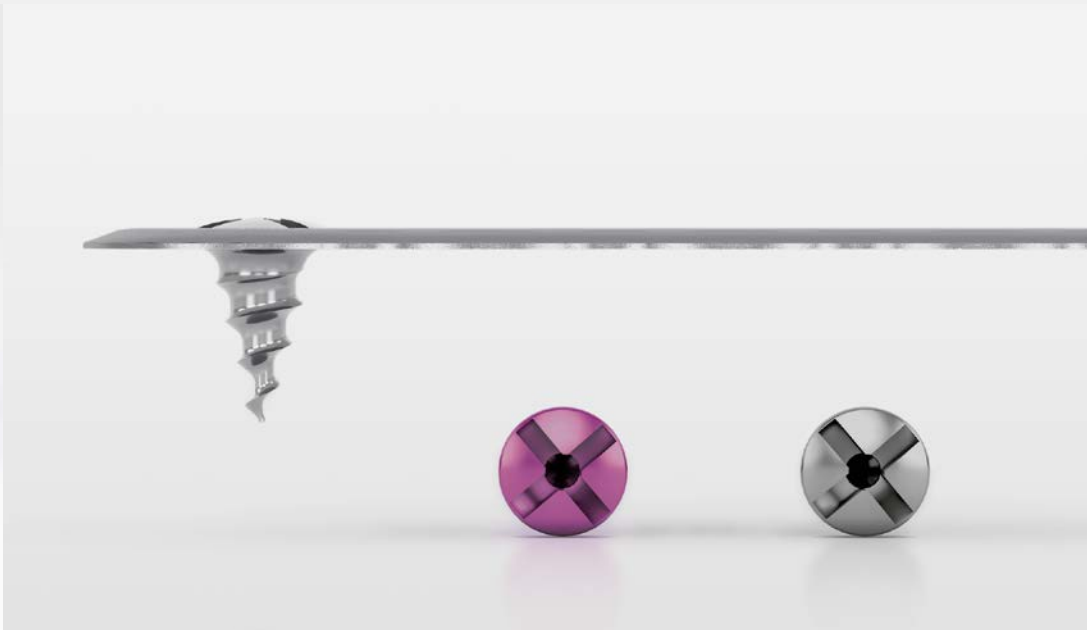
The plate design with self-aligning screw countersink is perfectly matched to the new 1.5 mm diameter oneDrive screws. Thus, the system convinces with a flush plate-screw combination.

Compared to standard implants, the profile thickness of 0.35 mm is significantly reduced. In combination with the rounded and atraumatic plate design, the ultraOne plates blend into the soft tissue and are therefore hardly palpable for the patient.

L1® Cranium – Plates

	Feature	Benefit
	■ Wide range of plates with different hole variants and geometries	■ Covers a wide range of indications ■ Sharp edges due to shortening of the plate are avoided
	■ Profile thickness 0.35 mm ■ Rounded atraumatic plate contour	■ Minimal palpability due to low plate-screw profile ■ High anatomical adaptability ■ Optimal embedding in soft tissue
	■ Breakaway tab with article number, batch number, GTIN number, and DataMatrix code	■ Facilitates positioning the plate on the bone ■ Enables reading or digital recording of all the relevant data ■ Batch traceability for every single plate
	■ DataMatrix code for scanning with a 2D code scanner	■ Easy recording of all the implant data by scanning the DataMatrix code ■ 100% batch traceability and transparent, patient-related documentation
	■ All plates are also available in individually sterile packaged versions ■ Including self-adhesive labels with all the relevant implant data	■ Comprehensive selection for the customer ■ 100% batch traceability and transparent, patient-related documentation

Feature, Function and Benefit



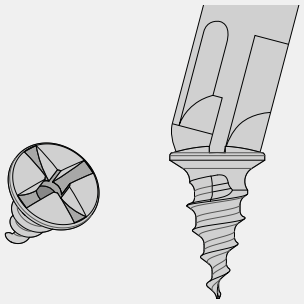
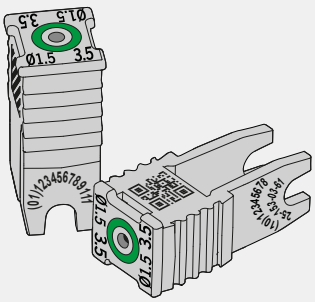
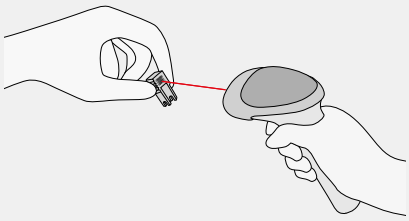
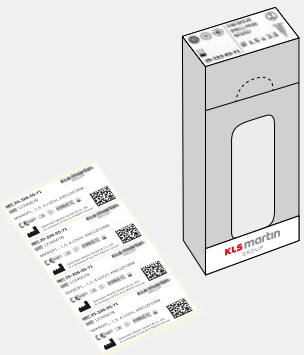
The oneDrive screws are characterized by a low profile with high stability of the screw head. They were developed specifically for the requirements of neuro osteosynthesis and hard cranial bone.

The self-drilling 1.5 mm diameter oneDrive screws can be combined with all ultraOne plates. The 1.8 mm diameter emergency screws can be used in case of insufficient bone quality.

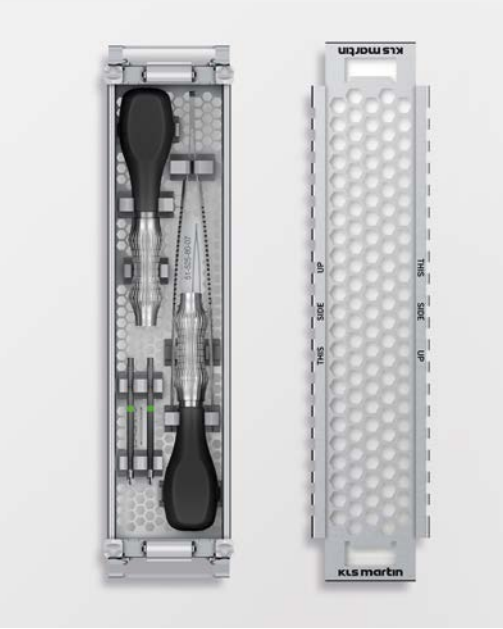
Color-coded single clips ensure clear identification of the diameters. When stored in the clip, the corresponding color coding of the screws makes it easy to determine whether it is a Drill-Free or emergency screw.

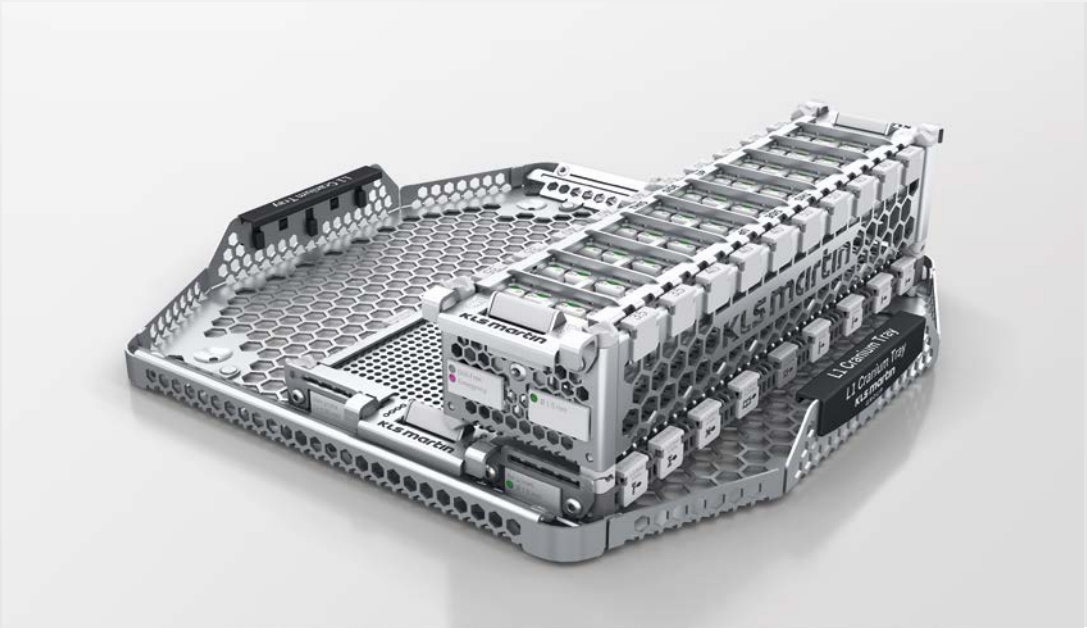
Color code	Screw type
Silver	Drill-Free screw
Pink	Emergency screw

L1® Cranium – Screws

	Feature	Benefit
	■ Self-retaining function ■ Self-drilling, optimized tip and thread flank design ■ Low screw head profile	■ Easy pick-up of the screw ■ Quick screwing in of the screw at low effort ■ Can be screwed in at an angle ■ Minimal palpabilty
	■ Screws in color-coded single clip with article number, batch number, GTIN number, and DataMatrix code	■ Clear assignment of respective screw diameters and lengths ■ Enables reading or digital recording of all the relevant data ■ Batch traceability of every single screw
	■ DataMatrix code for scanning with a 2D code scanner	■ Easy recording of all the implant data by scanning the DataMatrix code ■ 100% batch traceability and transparent, patient-related documentation
	■ All screws are available in individually sterile packaged versions ■ Including self-adhesive labels with all the relevant implant data	■ Comprehensive selection for the user ■ 100% batch traceability and transparent, patient-related documentation

Feature, Function and Benefit





The L1® Cranium System is rounded off by a space-saving storage concept which allows individual configurations due to its modular design. As an open solution with 100% batch traceability of each individual implant, the cleaning and sterilization-validated implant modules represent a true alternative to the sterile-packaged system.

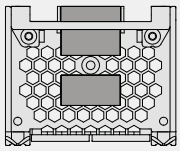
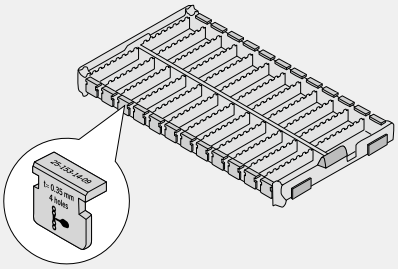
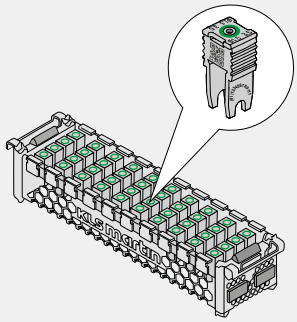
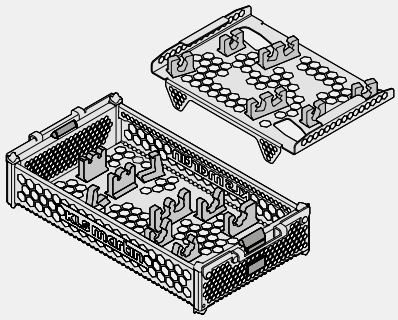
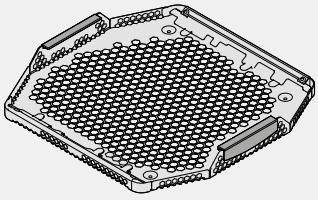
Two screwdrivers, two blades and a plate holding forceps can be stored in the Standard instrument module. All instruments required for classic cranial flap fixation are thus available in a compact form.

Additional storage space for two bending pliers and a mesh cutter is provided in the Comfort instrument module. The Comfort variant thus covers a broader range of indications.

If additional storage space is required for further instruments, the Universal free storage module is available.

To ensure safe and easy removal from the sterile container, as well as to optimize wrapping, the portfolio is completed with the tray.

L1® Cranium – Storage

	Feature	Benefit
	■ Stainless steel storage trays in honeycomb design combined with high-performance plastic	■ High strength, light weight ■ Good rinsing results due to large openings
	■ Each compartment in the plate module is marked with a labeling clip that bears the article number, the plate profile, and a picture of the plate. ■ Matt dark inner surface	■ Application-oriented access to the plate and intuitive refilling ■ Transparent arrangement ■ Increased contrast and good recognition of plates, even under surgical light
	■ Single screw clips can be taken out of the screw module from any position	■ Easy removal and refilling
	■ Instrument insert for bending pliers	■ Space-saving ■ Optionally available
	■ Tray without sharp edges ■ Spacer for modules	■ Ideal for use in the sterile container as well as with soft packaging ■ Modules are held in position and can be removed individually from the sterile container without compromising sterility

Step by Step to Optimal Care

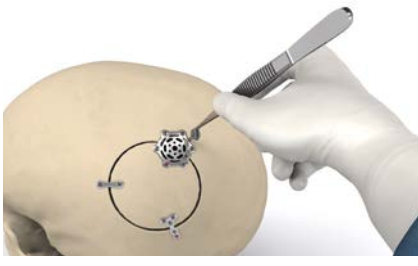
Fields of Use

The L1® Cranium System is used for fracture treatment, fixation of osteotomies and cranial flaps and for reconstructive procedures in the area of the skullcap.

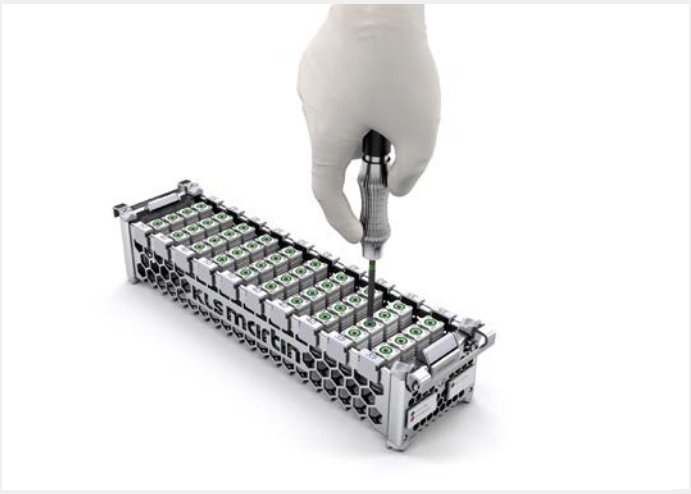
Surgical Techniques

1. Handling of the Instruments and Storage Pages 14 - 18

2. Cranial Fixation Pages 19 - 21



1. Handling of the Instruments and Storage



1.1. Assembly of the screwdriver

Connect the screwdriver blade with hex coupling to the screwdriver handle. To do this, pull the silver-colored serrated part of the handle backwards to insert the blade into the holder while maintaining this position. After insertion of the blade, release the serrated part and return it to its original position, thus ensuring secure anchoring of the blade.

Blades for 1.5 mm diameter screws are marked with a green ring.

1.2. Removing the screws from the screw module

Insert the tip of the screwdriver blade vertically into the head of the screw and pick up under axial pressure to ensure a secure grip.

After use, the empty individual screw clips can be taken out of the screw module from any position and refilled accordingly.

Collect the empty clips for later recording of the implant data.

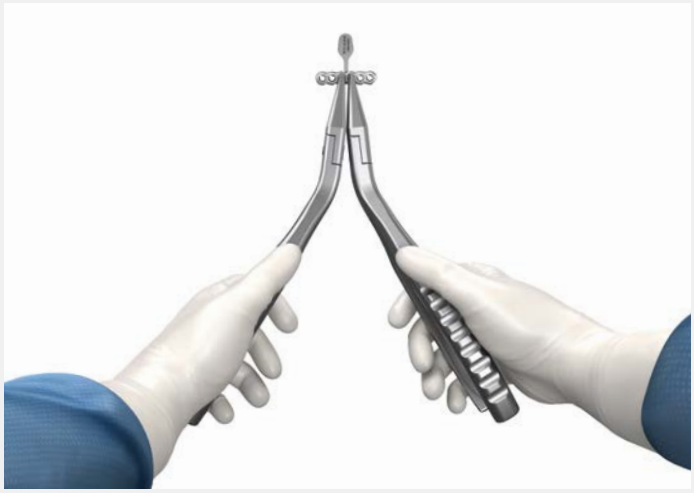
1.3. Checking the screw length

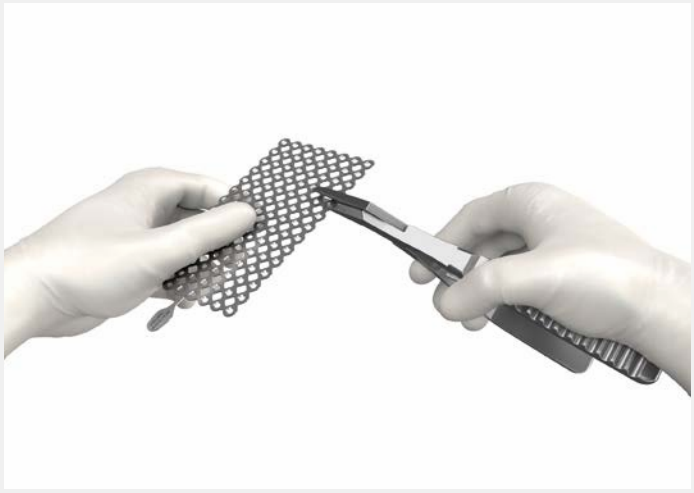
Check the screw length using the screw measuring clip.
The length can be read off at the head end of the screw.

1.4. Removing the plate from the plate module

Remove the plate from the plate module using forceps.

Collect the ID tags for later recording of the implant data.





1.5. Contouring the plate with the plate bending pliers

3D bending in multiple planes
You can adapt the plate by using the two bending pliers. To protect the plate holes, make sure that they are completely covered by the pliers and always hold the plate at two consecutive holes. Otherwise the contour of an intermediate hole can be damaged.

1.6. Cut the mesh with the mesh cutter

Position the area of the mesh to be cut between the cutting surfaces of the mesh cutter. Then operate the cutting instrument to cut the desired area of the mesh.

Precautions:
- When cutting small implant sections, place your hand loosely around the cutting area to prevent particles from falling into the surgical site.
- Sharp edges may need to be deburred.

1.7. Scanning the DataMatrix code

The single screw clip as well as the breakaway tab of the plates contain all the relevant data in readable plain text as well as encoded in a GS1 DataMatrix code:

- GTIN number
- Batch number

This way, the information can either be manually transferred to the patient file and used for reordering or it can be captured and further processed by scanning the DataMatrix code with a 2D code scanner.

The DataMatrix code can also be read with a smartphone or the "iGepir" app provided by GS1 Germany.

1.8. GTIN number

The GTIN number (Global Trade Item Number) clearly identifies articles worldwide. It acts as an access key to the product information stored in databases, such as, for example, the product designation and weight.

Additionally, variable data are added to the GTIN number using GS1 application identifiers. In the case of KLS Martin, this is the batch number, and for sterile packaged products, the expiry date.

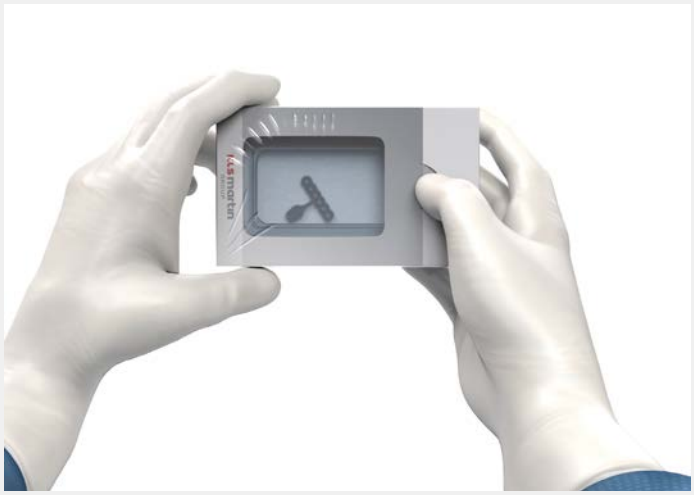
Configuration for sterile packaged implants:

➔ **(01)**123456789111**(17)**251210**(10)**12345678

GTIN number	**Expiry date (e.g. 10.12.2025)**	**Batch number**
(01)123456789111	**(17)**251210	**(10)**12345678
↑	↑	↑

GS1 application identifier, a unique identifier for the respective product information:

01 – always initiates the GTIN number
17 – always initiates the expiry date
10 – always initiates the batch number



1.9. Sterile packaging

Both the plates and the screws are available as single sterile-packed versions.

The cardboard packaging is opened by pressing the thumb into the perforation. The outer protective film also comes off in the process. The double sterile barrier is achieved by two blisters. Open the blisters by pulling off the Tyvek at the tab.

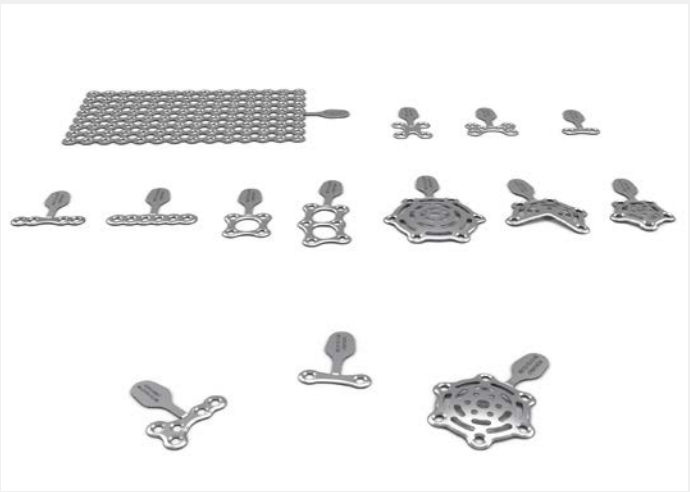
1.10. Removal of the modules from the sterile container

The modules are held in position in the tray by the spacers. This lets you remove the modules individually from the container without compromising sterility.

In addition, the tray features markings to enable you to place the modules intuitively.

The handles on the tray serve to remove the tray from the sterile container when empty.

2. Cranial Fixation



2.1. Patient positioning and approach

Place the patient in supine position on the operating table. Normally, a nasotracheal intubation is implemented.

The type of access should be chosen depending on the indication, as a craniotomy may be required for a variety of reasons.

After preparing the skin, use a trephine drill to gain access to the bone flap. Then use a craniotome with dura guard to remove the bone flap.

Use the L1® Cranium System to reattach the bone flap osteosynthetically upon completion of surgery.

2.2. Selection of osteosynthesis plates

We recommend using at least three plates with fully occupied screw holes for bone flap fixation. The following illustrates an example for a cranial flap fixation with:

- ultraOne burr hole cover, Ø 18 mm
- ultraOne plate, straight, 2-hole, long
- ultraOne Y-plate, 5-hole

2.3. Positioning the plates on the bone flap

Hold the plates in position using the plate holding forceps.

When positioning the plates, always make sure that the countersunk holes face upwards.

2.4. Fixation of plates to the bone flap

Connect the blade to the screwdriver handle.

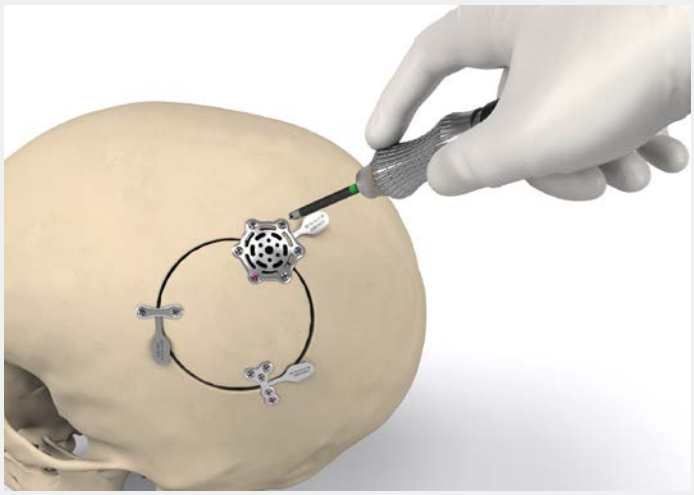
In the next step, pick up the self-drilling 1.5 mm diameter oneDrive screws by applying axial pressure with the blade, and remove them from the module. Then screw the screws vertically into the plate holes to secure the plate to the bone flap. If a screw does not grip, then 1.8 mm diameter emergency screws with the same screw length are available. Occupy all existing screw holes without tightening them completely.

Before fixation, check the screw length using the screw measuring clip. This prevents damage to underlying structures if the selected screws are too long. Furthermore, this could lead to loosening or migration of the plates.

Plate holding forceps

Screwdriver handle, flat, rotatable

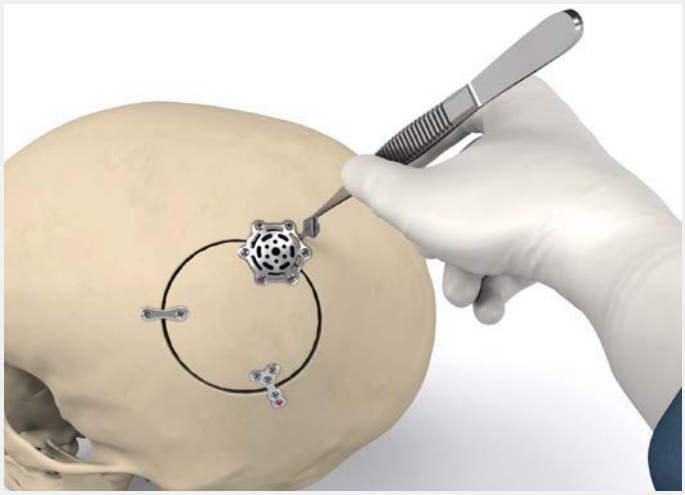
oneDrive blade
Ø 1.5 mm



2.5. Closing the skullcap

Place the bone flap in the skullcap and secure with screws. Then retighten all screws.

After closing the skullcap, you may need to irrigate and suction the area to remove debris that may have occurred during implantation.



2.6. Removing the Breakaway tab

As a final step, use the plate holding forceps to remove the Breakaway tab from the plates by repeatedly moving it back and forth.

The tabs ensure 100% batch traceability and transparent, patient-related documentation.

Screwdriver handle, flat, rotatable

oneDrive blade
Ø 1.5 mm

Plate holding forceps

Implants **L1®** Cranium –
1.5 ultraOne Plates in Profile Thickness 0.35 mm

ultraOne plate, straight,
2-hole, short

25-153-02-09 Ti 1
25-153-02-71 Ti 1

= 0.35 mm

ultraOne plate, straight,
2-hole, long

25-153-12-09 Ti 1
25-153-12-71 Ti 1

= 0.35 mm

ultraOne plate, straight,
4-hole

25-153-14-09 Ti 1
25-153-14-71 Ti 1

= 0.35 mm

ultraOne plate, straight,
6-hole

25-153-08-09 Ti 1
25-153-08-71 Ti 1

= 0.35 mm

ultraOne X-plate,
4-hole

25-153-01-09 Ti 1
25-153-01-71 Ti 1

= 0.35 mm

ultraOne Y-plate,
5-hole

25-153-07-09 Ti 1
25-153-07-71 Ti 1

= 0.35 mm

ultraOne double Y-plate,
6-hole

25-153-06-09 Ti 1
25-153-06-71 Ti 1

= 0.35 mm

ultraOne grid plate,
2 x 2-hole

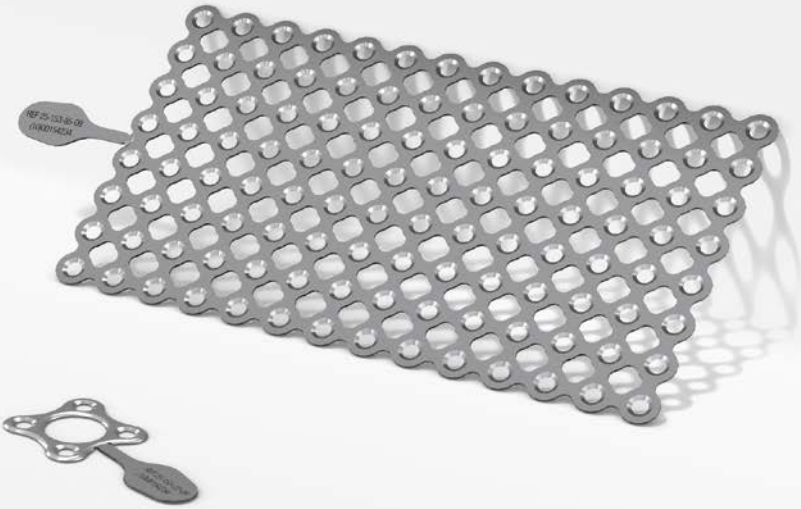
25-153-22-09 Ti 1
25-153-22-71 Ti 1

= 0.35 mm

ultraOne grid plate,
3 x 2-hole

25-153-32-09 Ti 1
25-153-32-71 Ti 1

= 0.35 mm



Explanation of icons

- Ti — Pure titanium
- Ti — Titanium alloy
- 1 — Units per package
- Plate profile
- STERILE — Sterile packaged implants

1/1

ultraOne burr hole cover,
Ø 12 mm

25-153-15-09 Ti 1
25-153-15-71 Ti 1

= 0.35 mm

1/1

ultraOne burr hole cover, drain,
Ø 18 mm

25-153-20-09 Ti 1
25-153-20-71 Ti 1

= 0.35 mm

1/1

ultraOne burr hole cover,
Ø 18 mm

25-153-21-09 Ti 1
25-153-21-71 Ti 1

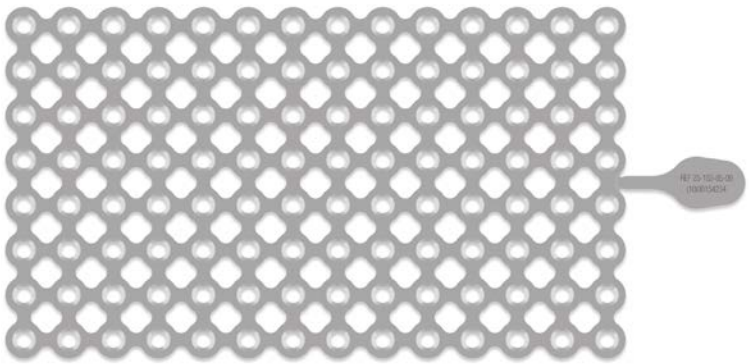
= 0.35 mm

1/1

ultraOne burr hole cover,
Ø 23 mm

25-153-25-09 Ti 1
25-153-25-71 Ti 1

= 0.35 mm



1/1

ultraOne Mesh,
85 x 50 mm

25-153-85-09 Ti 1
25-153-85-71 Ti 1

= 0.35 mm

Implants **L1®** Cranium – oneDrive Screws in Single Clips

oneDrive

Drill-free screws Ø 1.5 mm
self-retaining, self-drilling

Ø x Length	non-sterile	STERILE
1.5 x 3.5 mm	25-153-03-61	25-153-03-71
1.5 x 4 mm	25-153-04-61	25-153-04-71
1.5 x 5 mm	25-153-05-61	25-153-05-71

Emergency screws Ø 1.8 mm
self-retaining

Ø x Length	non-sterile	STERILE
1.8 x 4 mm	25-153-44-61	25-153-44-71
1.8 x 5 mm	25-153-45-61	25-153-45-71

Instruments **L1®** Cranium –
Instrumentation Standard and Comfort

Explanation of icons

- Ti — Titanium alloy
- St — Steel
- Sic — Silicone
- oneDrive
- System diameter 1.5 mm
- 1 — Units per package
- STERILE — Sterile packaged implants

Instrumentation Standard and Comfort

½

51-525-80-07

15.5 cm / 6 ⅛"
Plate holding forceps

St 1

½

25-407-04-04

11 cm / 4 ⅜"
Screwdriver handle, flat, rotatable
(2 per set)

St 1 Sic

½

25-439-91-07

5.8 cm / 2 ⅜"
oneDrive blade
(2 per set)
Ø 1.5 mm

St 1

½

55-990-34-04

2.3 cm / ⅞"
Screw measuring clip
oneDrive

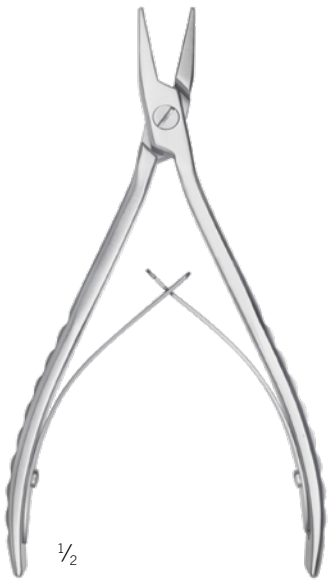
1

Instruments **L1®** Cranium – Instrumentation Comfort and Additional Instrumentation Mesh

Instrumentation Comfort

25-052-13-07
13 cm / 5 ⅛"
Mesh cutter

St 1



25-516-14-07
15.5 cm / 6 ⅛"
Bending pliers, curved
(2 per set necessary)

St 1

Explanation of icons

St Steel

1 Units per package

Additional Instrumentation Mesh - can be stored in the Universal Instrument Module

25-050-98-07

Set of spare blades

½

25-050-00-07

19.4 cm / 7 ⅝"

Mesh cutter

St 1

½

25-052-18-07

18 cm / 7“

Mesh bending pliers

St 1

Storage **L1®** Cranium –
The Concept for Non-sterile and Sterile Packaged Implants

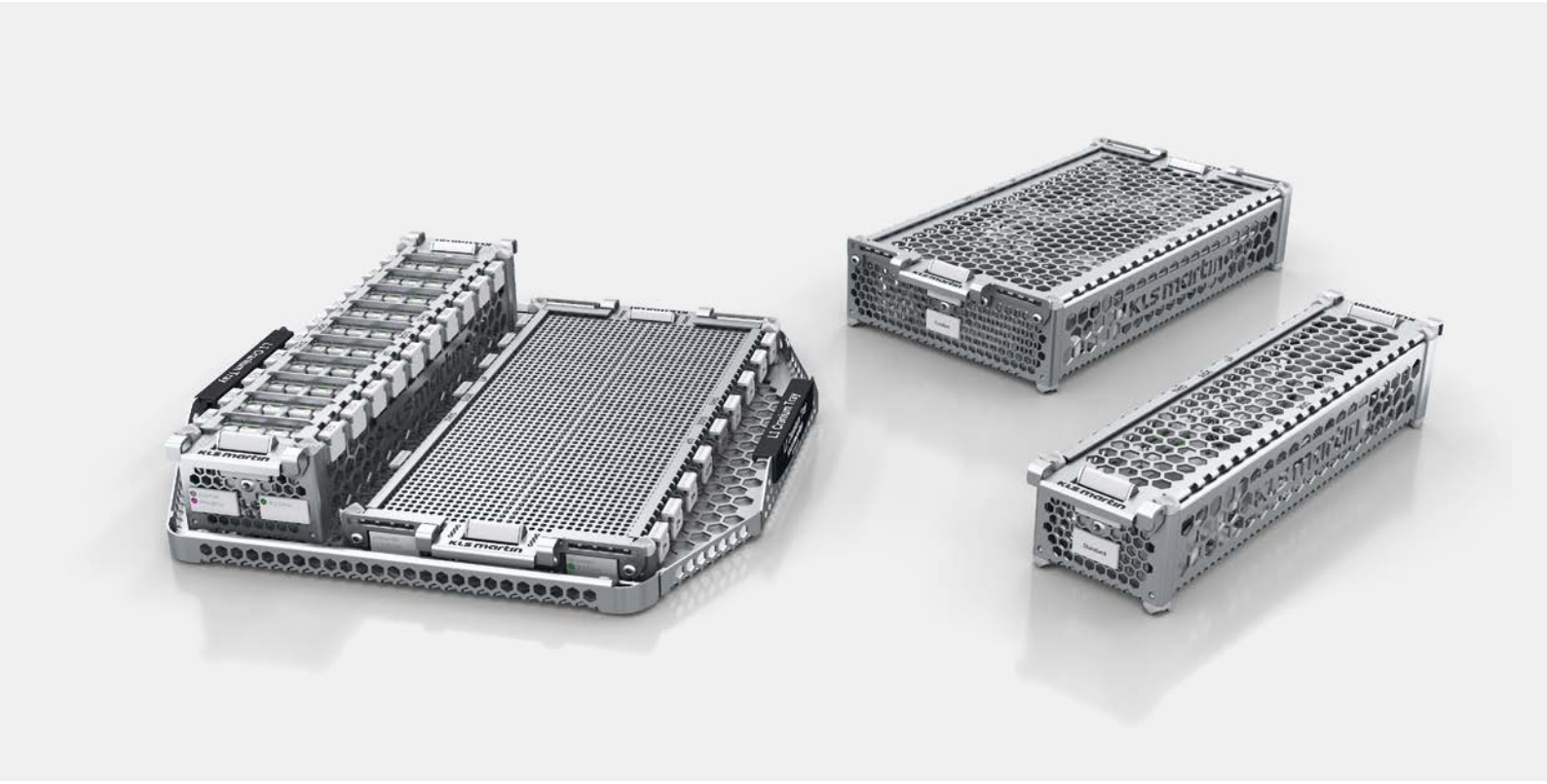
The KLS Martin storage concept, which is specifically adapted to maxillofacial surgery, is made of stainless steel in honeycomb design combined with high-performance plastic, and not only ensures high stability at low weight, but also results in excellent rinsing capability.

All implant modules, both plate and screw modules, are cleaning and sterilization validated and suitable for machine reprocessing. They thus meet the requirements for optimal reprocessing.

For transparent organization and easy identification all the module fronts have color-coded labeling clips that clearly indicate the contents.

The screw module can accommodate a total of 40 screws stored in single clips. A screw measuring clip can be integrated in the module as an option.

In the plate module the plates are clearly arranged and kept separate from each other. Each plate compartment is marked at the side with a labeling clip that bears the article number, the profile, and a picture of the plate. As a result, the necessary information is provided for application-oriented access and intuitive refilling.



The Standard and Comfort instrument modules are equipped with silicone bars which provide each instrument with its own storage location. To be able to store the instruments safely in the free storage space of the L1 Universal instrument module, the module is equipped with a studded mat.

The stackable modules, which are matched in size, make it possible to create customized set designs in a simple and practical manner. The rounded tray optimizes handling of the modules during the sterilization process.

Apart from the option of conventional storage, the L1® Cranium System is also available with sterile packaged implants throughout.

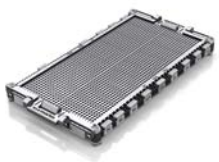
L1® Cranium – Storage

Set Option 1	
55-990-31-04	L1® Cranium screw module for Ø 1.5 oneDrive Drill-Free and Ø 1.8 oneDrive emergency screws
55-990-32-04	L1® Cranium plate module for 1.5 ultraOne plates in profile thickness 0.35 mm
55-990-35-04	L1® Cranium instrument module Standard

Set Option 2	
55-990-31-04	L1® Cranium screw module for Ø 1.5 oneDrive Drill-Free and Ø 1.8 oneDrive emergency screws
55-990-32-04	L1® Cranium plate module for 1.5 ultraOne plates in profile thickness 0.35 mm
55-990-36-04	L1® Cranium instrument module Comfort
55-990-29-04	L1® Cranium insert Comfort

L1® Cranium Implant Storage	
55-990-31-04	L1® Cranium screw module for Ø 1.5 oneDrive Drill-Free and Ø 1.8 oneDrive emergency screws Configured for: Drill-Free: 8 x 3.5 mm, 12 x 4 mm, 8 x 5 mm Emergency screws: 8 x 4 mm, 4 x 5 mm (40 screw single clips)

L1® Cranium Implant Storage	
55-990-32-04	L1® Cranium plate module for 1.5 ultraOne plates in profile thickness 0.35 mm

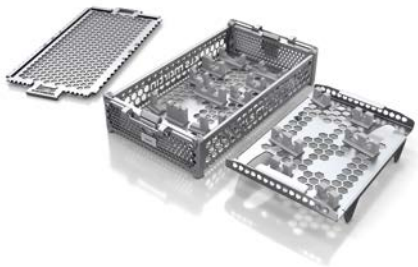


Option 1: Standard

L1® Cranium Instrument Storage	
55-990-35-04	L1® Cranium instrument module Standard

Option 2: Comfort

L1® Cranium Instrument Storage	
55-990-36-04	L1® Cranium instrument module Comfort
55-990-29-04	L1® Cranium insert Comfort



Optional

L1® Cranium Instrument Storage	
55-990-33-04	L1® Cranium tray

L1® Cranium Instrument Storage	
55-990-30-04	L1® Cranium instrument module Universal

KLS Martin Group

KLS Martin Australia Pty Ltd.
Sydney · Australia
Tel. +61 2 9439 5316
australia@klsmartin.com

KLS Martin do Brasil Ltda.
São Paulo · Brazil
Tel. +55 11 3554 2299
brazil@klsmartin.com

KLS Martin Medical (Shanghai) International Trading Co., Ltd
Shanghai · China
Tel. +86 21 5820 6251
info@klsmartin.com

KLS Martin India Pvt Ltd.
Chennai · India
Tel. +91 44 66 442 300
india@klsmartin.com

KLS Martin Italia S.r.l.
Milan · Italy
Tel. +39 039 605 67 31
info@klsmartin.com

KLS Martin Japan K.K.
Tokyo · Japan
Tel. +81 3 3814 1431
info@klsmartin.com

KLS Martin SE Asia Sdn. Bhd.
Penang · Malaysia
Tel. +604 261 7060
malaysia@klsmartin.com

KLS Martin de México, S.A. de C.V.
Mexico City · Mexico
Tel. +52 55 7572 0944
mexico@klsmartin.com

KLS Martin Nederland B.V.
Huizen · Netherlands
Tel. +31 35 523 45 38
infonl@klsmartin.com

KLS Martin SE & Co. KG
Moscow · Russia
Tel. +7 499 792 76 19
russia@klsmartin.com

KLS Martin Taiwan Ltd.
Taipei · Taiwan
Tel. +886 2 2325 3169
taiwan@klsmartin.com

KLS Martin SE & Co. KG
Dubai · United Arab Emirates
Tel. +971 4 454 16 55
middleeast@klsmartin.com

KLS Martin UK Ltd.
Reading · United Kingdom
Tel. +44 118 467 1500
info.uk@klsmartin.com

KLS Martin LP
Jacksonville · Florida, USA
Tel. +1 904 641 77 46
usa@klsmartin.com

KLS Martin SE Asia Sdn. Bhd.
Hanoi · Vietnam
Tel. +49 7461 706-0
info@klsmartin.com

KLS Martin SE & Co. KG
A company of the KLS Martin Group
KLS Martin Platz 1 · 78532 Tuttlingen · Germany
PO Box 60 · 78501 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com

91-350-12-02 · Rev. 02 · 2024-02