stryker®

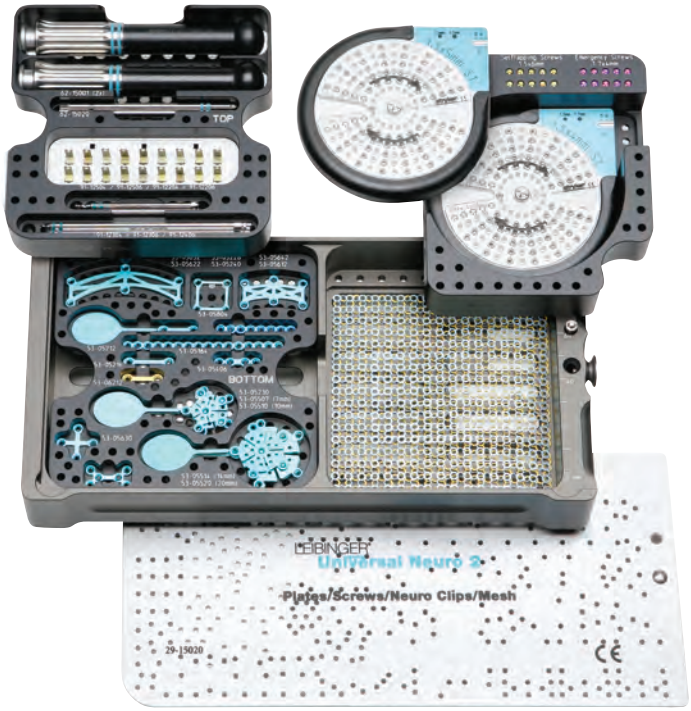
Craniomaxillofacial

Universal Neuro 2

Low Profile Fixation System

A Legacy of Serving the Surgical Community

For over half a century, Stryker has been developing products based on the expressed needs of leading practitioners.



When Dr. Homer Stryker, an orthopaedic surgeon from Kalamazoo, Michigan, found that certain medical products were not meeting his patients' needs, he invented new ones. From modest beginnings in the 1930s, Stryker has applied an innovative spirit and focus on patients to create breakthrough products that improved patient outcomes. Across the world in Mühlheim-Stetten, Germany, Oswald Leibinger sought to design and make surgical tools and clamps of unmatched quality and precision. Beginning in the 1950s, Leibinger's company established a reputation as a source for high quality surgical tools and micro instruments essential to the pioneers of Craniomaxillofacial surgery. Today these two famous names in medical device development are poised to bring innovation to the future of Craniomaxillofacial surgery.

Superior Quality, Lasting Innovation

Our products are derived from a close working partnership with surgeons, physicians and healthcare experts from the entire spectrum of the healthcare field. That has been the basis of success for nearly eight decades and will continue to foster success into the future.

A Partner in Creating the Future of CMF Surgery

We know our efforts make a difference. We also know that everything can be improved and we constantly seek to do just that. We strive to make our customers successful by working on their behalf. We partner with surgeons and medical professionals who are leaders in their field to advance medical care.

Our mission is to deliver health. By supporting and partnering with our customers, we can affect not only the health of the patient but touch upon the health of all the stakeholders in medicine.


We take
the work
seriously
for in the end
we help
make a difference
in people's lives

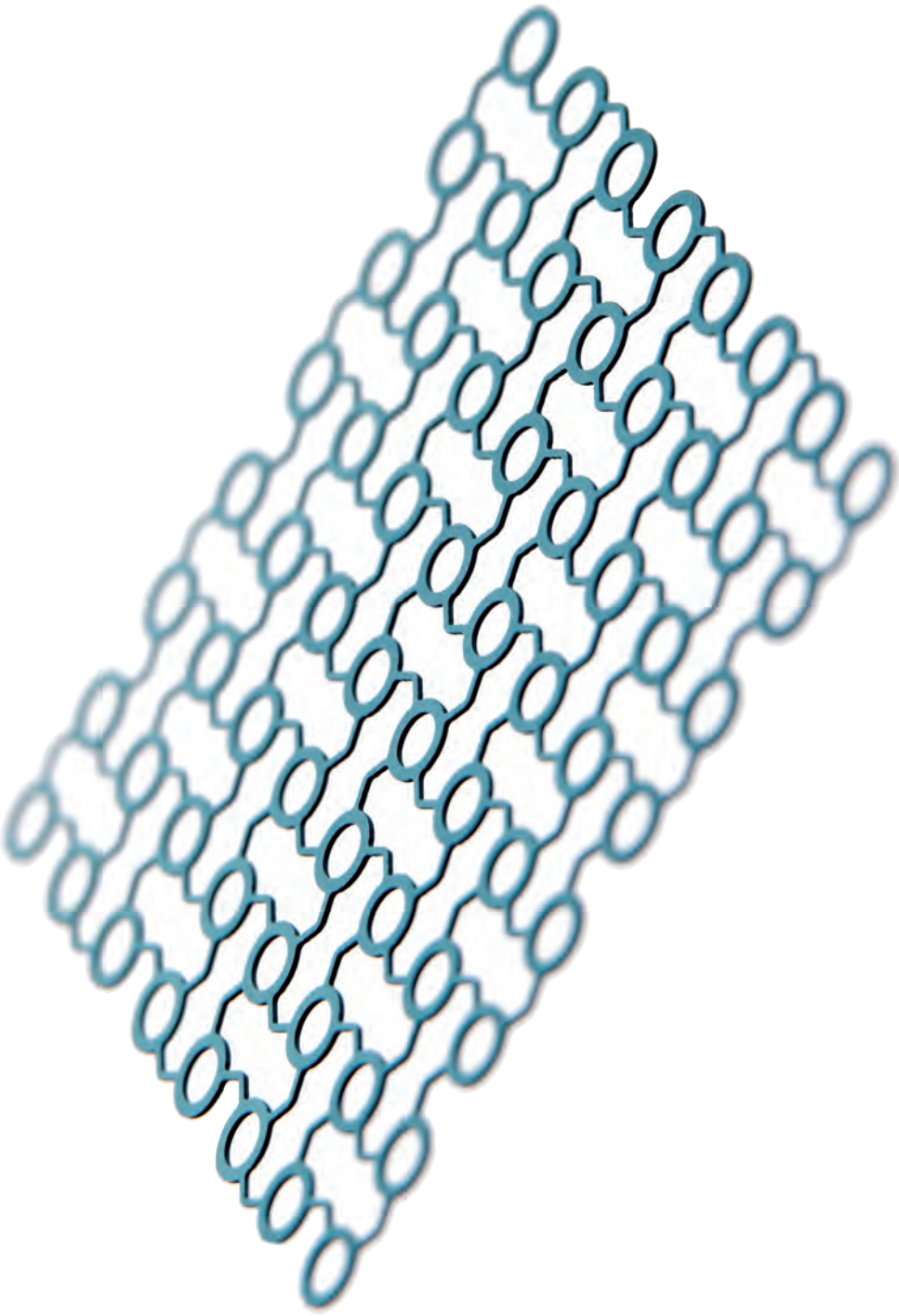


Table of Contents

Quality Commitment

Leibinger Tradition

Leibinger Universal Neuro 2

Leibinger was one of the first companies to introduce a titanium mini plating system for cranial and maxillofacial applications. Leibinger's innovation and quality set industry standards.

The Leibinger tradition continues today with novel design and manufacturing to the highest quality criteria. Quality manufactured in Germany.
Stryker's Leibinger products continue to push the limits in quality and safety.

Every screw that leaves the Freiburg facility goes through a microscopic quality control inspection. 100% quality control that clinicians benefit from.
As part of the continued commitment to quality and safety, the Leibinger Universal Neuro 2 System is now offered additionally in sterile packaging. For improved traceability and, ultimately, for surgeon and patient safety.

Overview

Solution Oriented

The Leibinger Universal Neuro 2 Plating System is a small set with a wide selection of solutions for cranial fixation. It is designed to fulfil the neurosurgical team's key needs:

- Excellent screw insertion
- Low profile plates and mesh for all major cranial indications
- Easy handling

Whether covering burr holes, bridging larger defects, or fixating fractures or cranial flaps, this set offers multiple alternative solutions for each indication:

- Malleable and rigid plates
- Meshes in multiple strengths and sizes
- Burr hole cover plates
- Gap plates
- Long straight plates for cutting to size
- 3D plates

To ensure ease of use, any plate can be used with any screw in the set.
It is an attractively laid out set that offers complete colour coding of plates, drill bits, screwdriver blades and screw disks as a guide for OR staff.
An additional instrument set for cutting and bending implants is available.

Implant Options

Indications for use

The **Leibinger Universal Neuro 2** System is a low profile plate and screw system. It is intended for osteotomy, craniotomy, stabilization and rigid fixation of craniofacial fractures and reconstruction of non-load bearing areas.

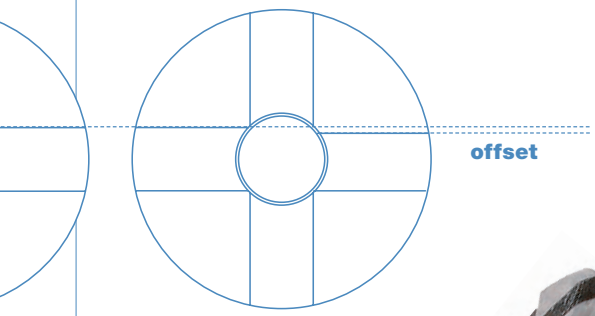
1.5 mm Neuro Screw

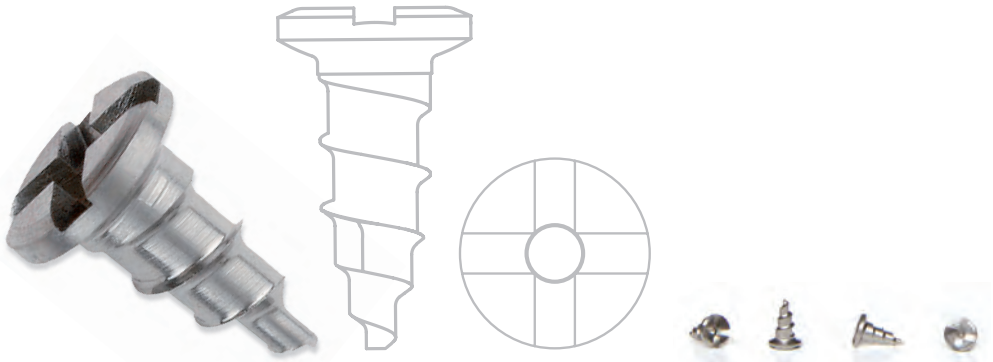
Extensive research and development has yielded an enhanced self-drilling screw specifically designed for insertion into cranial bone:

- Patented* screw tip design
- Conical core design

Screw to blade retention is optimzed with cross pin design to facilitate easy screw loading and insertion:

- Improved torque transmission
- Easy disengaging after screw insertion
- Low profile screws minimize palpability of implants.





Self-Drilling screw design with cross pin

* EP 1 547 535, other patents pending

Screw Disks

Screw Disk

- Disks are offered in non-sterile pre-loaded and empty versions
- Optimized design for easy screw pick up
- Storage of up to 80 screws allowing access to 5 screws at a time
- Re-sterilisable in the implant module

QuikDrive mini

QuikDrive mini is a battery powered screwdriver for inserting Leibinger titanium screws.

It has touch sensors for fingertip control when inserting or backing out screws.

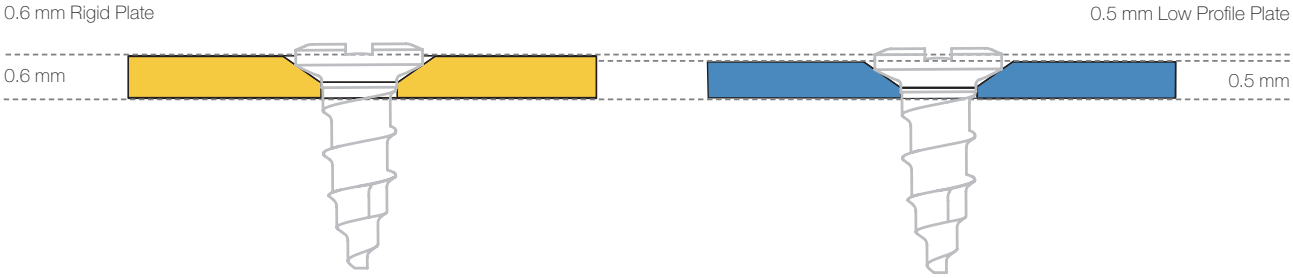
Implant Options

Low Profile Plates

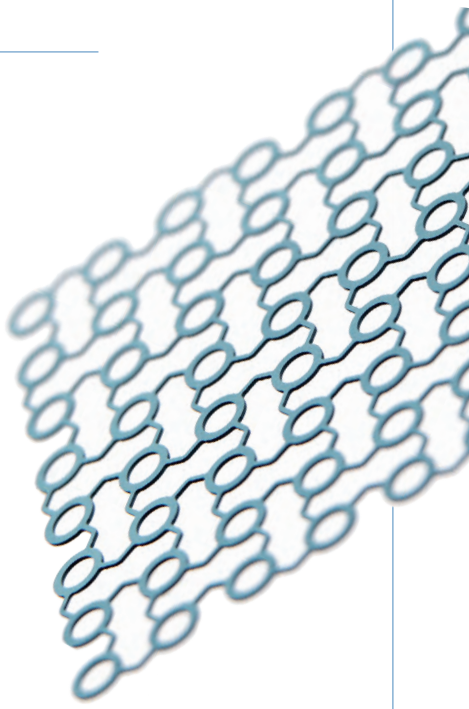
- Designed for fixation of cranial flaps with decreased palpability.
- Comprehensive selection of burr hole covers, straight plates, gap plates, 3D-plates and box plates to provide many fixation options.
- Selected plates feature break off tabs for improved handling.
- Malleable plates can be contoured by hand without instruments.

0.6 mm Rigid Plate

0.5 mm Low Profile Plate



Meshes



Titanium Meshes

The set offers storage possibilities for multiple mesh types:
Micro Mesh and Dynamic Mesh in a range of sizes.

Dynamic Mesh

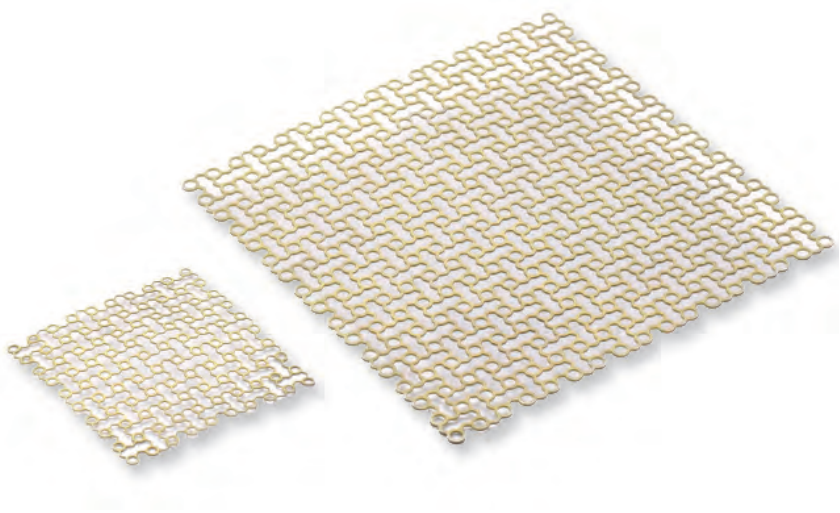
Dynamic Mesh facilitates three dimensional contouring while maintaining adequate fixation of bony defects of varied size and location. Dynamic Mesh can be shaped to most three dimensional bone. Dynamic Mesh is available in two types:

- Standard **(gold)**, 0.6 mm profile height
- Malleable low profile **(blue)**, 0.3 mm profile height

Micro Mesh

Micro Mesh is an ultra thin titanium mesh used for defect bridging of the skull and skull base, especially after tumor removal. It is available in two types:

- Standard **(gold)**, 0.2 mm thickness
- Malleable **(blue)**, 0.1 mm thickness



Mesh Bender

For bending of titanium mesh to the required contour.

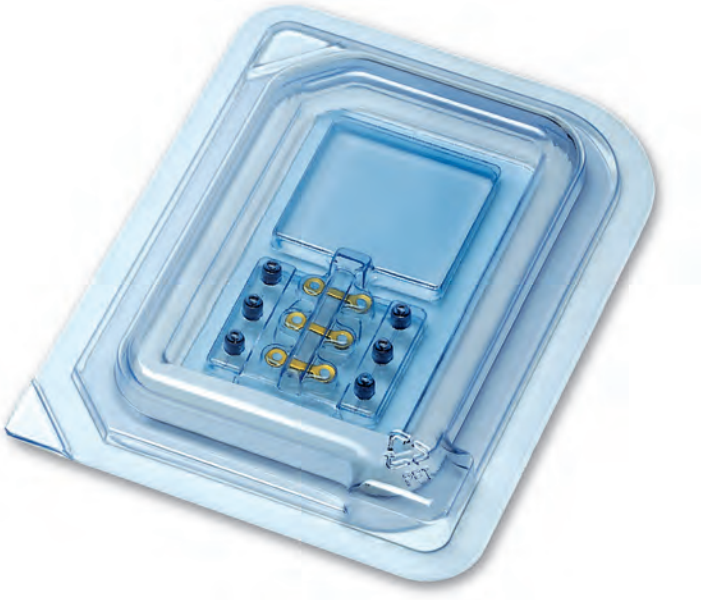
Implant Options

NeuroClip Driver

The NeuroClip is designed for cranial bone flap fixation. Application is simple with minimal instrumentation.
The NeuroClip can be applied to the cranial bone flap while the dura mater is being closed, resulting in improved safety and time savings.
The spike of the clip is firmly inserted into the diploe in the bone flap with the clip driver. A 1.5 mm neuro screw provides stability for each NeuroClip in the surrounding cranial bone.
The use of at least three NeuroClips and screws are recommended for bone flap fixation.

QuikFlap

As a simple to use alternative, Stryker also offers QuikFlap procedure packs for cranial bone flap and cranial trauma fixation. The QuikFlap packs contain three 2-hole plates and six 1.5 mm neuro screws. These are offered in self-tapping and self-drilling versions. The implants can be fixated to the cranial bone flap on a sterile table while the dura is being closed. QuikFlap is a practical and disposable solution to cranial fixation. All that is required in additional instrumentation is the 1.5 mm neuro screwdriver, or the QuikDrive mini battery powered screwdriver.



Implant Storage

Implant Module

The module consists of three lift out inlays for self-explanatory lay out and easy access to all components.

Module

1. Plate inlay for storage of plates
2. Instrument inlay for screwdrivers and drill bits
3. Disk inlay for storage of up to two screw disks plus emergency screws
4. Mesh up to 90 x 90 mm can be stored in the implant module under the screw disk inlay

Sterile Implants

Safety and Traceability

Sterile packed implants offer the twin advantages of decontaminated, sterile implants and improved traceability of product from patient back to the raw material.

- Implants are packed in a double blister pack
- Plates are packed single
- Screws are available in single and multiple packs of four

Sterile implants can contribute to:

- Savings through a rationalization of implant inventory
- Savings in set reprocessing and resterilization costs

Instruments

Design for Use

The instrument set offers a selection of high quality Leibinger instruments for picking up, adapting and cutting plates and meshes as required. There is also space for additional screwdriver handles, blades, mesh benders and the NeuroClip Driver. The instrument tray with lid offers an appropriate solution for users of sterile implants.

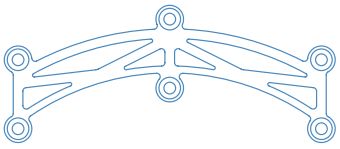
All required instruments can be stored and sterilized in this closed tray. Plates, screws and drill bits are available sterile. The instrument tray itself has dedicated space for each instrument marked with engravings for easy handling post-op and in central sterilization.

Technical Details

R&D efforts for a better clinical outcome

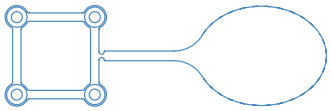
Plate Manufacturing & Finishing

Plates are lasered from sheets of commercially pure titanium. A special laser process helps minimize oxidization during the cutting process in order to reduce the changes to the original titanium ductility. The clinical advantage – a plate which can adapt to the required anatomy. After lasering, all plates are deburred and the edges finished to avoid the risk of soft tissue irritation.



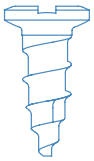
Plates with Tabs

Tabs serve as an assistance to placement of the plate whilst placing the first screws. In order to enhance tap removal, the plates are manufactured from the most malleable medical grade I titanium and a narrower breakoff point is prepared.



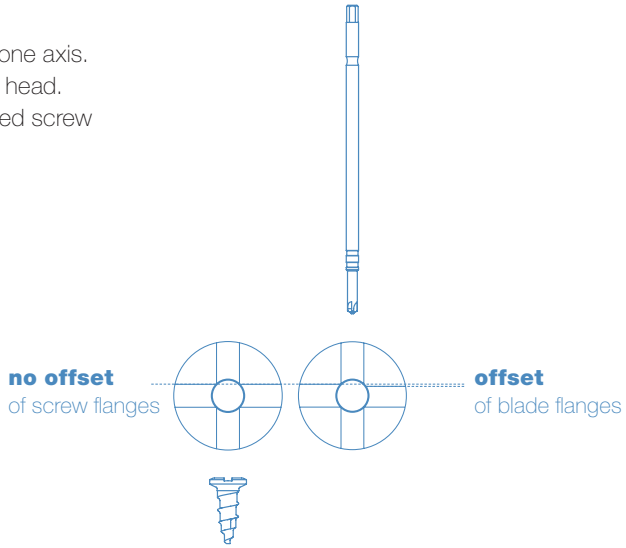
Screw Design

The self-drilling neuro screw is specifically designed for the hard cranial bone structure. It is manufactured from grade V titanium alloy for greater strength. The screw has a strongly tapered core and a patented tip design for excellent screw insertion. A wide thread pitch enables quick insertion with fewer turns.



Precision Manufacturing

The flanges of the screwdriver blade are offset from each other by in one axis. This creates 'friction fit' connection between the blade and the screw head. Neuro surgeons involved in early clinical evaluation of the implants rated screw pick up and insertion as excellent.



Modularity

Configure the set to meet your needs!

A neuro plating set in multiple configurations to ensure practical ease of use for the OR team. Order only what you need. In the configuration of your choice.

Module Only

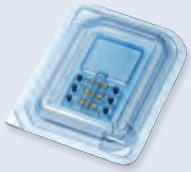
For regular autoclave sterilization of implants and minimal instrumentation

Complete Set

Implant module, instrument tray and storage container

Quarter Tray

Implant module plus a



Instrument Set

For use with sterile packed implants & drill bits

Combined Tray

Storage of the implant module, instruments
and large sized Dynamic Mesh up to 200 x 200 mm

additional bending and cutting instrumentation

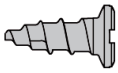
Ordering Information

Implants

Neuro Screws

1.5 mm Self-Drilling Screws

illustrated scale 3 : 1



REF	Length	Quantity
50-15904	4 mm	5 pack non-sterile
21-15904		1 pack sterile
24-15904		4 pack sterile
50-15905	5 mm	5 pack non-sterile
21-15905		1 pack sterile
24-15905		4 pack sterile

1.5 mm Self-Tapping Screws

illustrated scale 3 : 1

REF	Length	Quantity
50-15004	4 mm	5 pack non-sterile
21-15004		1 pack sterile
24-15004		4 pack sterile
50-15005	5 mm	5 pack non-sterile
21-15005		1 pack sterile
24-15005		4 pack sterile
50-15006	6 mm	5 pack non-sterile
21-15006		1 pack sterile
24-15006		4 pack sterile

1.7 mm Self-Tapping Emergency Screws

illustrated scale 3 : 1

REF	Length	Quantity
50-17304	4 mm	5 pack non-sterile
21-17304		1 pack sterile

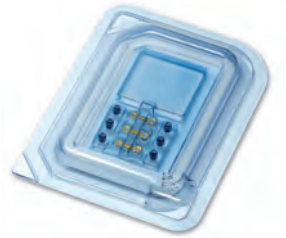
Grey item numbers reference sterile products

NeuroClip

illustrated scale 1 : 1

REF	Description	Quantity
54-05100	NeuroClip 1.5 mm / 1.7 mm	1 pack single

Universal QuikFlap



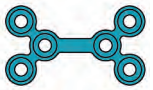
REF	Description	Contents
12-01502	QuikFlap 1.5 x 4 mm Screws self-drilling	3 x **53-06212** (Plate) 6 x **50-15904** (Screw)
12-01512	QuikFlap 1.5 x 4 mm Screws self-tapping	3 x **53-06212** (Plate) 6 x **50-15004** (Screw)

Ordering Information

Implants

Plates (all single packed)

illustrated scale 1 : 1

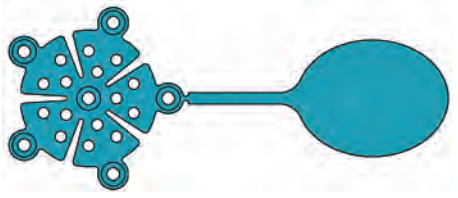


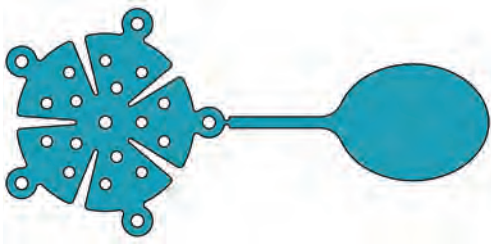
REF	Description
53-05804 **13-05804**	Low Profile Plate, straight, 8 hole sterile
53-05164 **13-05164**	Low Profile Plate, straight, 16 hole sterile
53-05406 **13-05406**	Low Profile Plate, 4 hole, 6 mm bar sterile
53-06212 **13-06212**	Plate rigid, 2 hole, 12 mm bar sterile
53-05212 **13-05212**	Low Profile Plate, 2 hole, 12 mm bar with Tab sterile
53-05216 **13-05216**	Low Profile Plate, 2 hole, 16 mm bar sterile
53-05228 **13-05228**	Low Profile Plate, 3-D Box Plate, 2x2 hole sterile
53-05608 **13-05608**	Low Profile Double-Y-Plate, 6 hole, bar sterile
53-05612 **13-05612**	Low Profile Gap Plate, small sterile
53-05622 **13-05622**	Low Profile Gap Plate, large sterile
53-05630 **13-05630**	Low Profile X-Plate, 4 hole sterile

Grey item numbers reference sterile products

Plates (all single packed)

illustrated scale 1 : 1





REF	Description
53-05230 **13-05230**	Low Profile 3-D Box Plate, 2 x 2 hole, Tab sterile
53-05240 **13-05240**	Low Profile 3-D Box Plate, 2 x 2 hole, large sterile
53-05507 **13-05507**	Low Profile Burr Hole Cover 7 mm, with Tab sterile
53-05510 **13-05510**	Low Profile Burr Hole Cover 10 mm, with Tab sterile
53-05514 **13-05514**	Low Profile Burr Hole Cover 14 mm, with Tab sterile
53-05520 **13-05520**	Low Profile Burr Hole Cover 20 mm, with Tab sterile

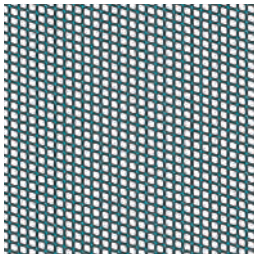
Grey item numbers reference sterile products

Ordering Information

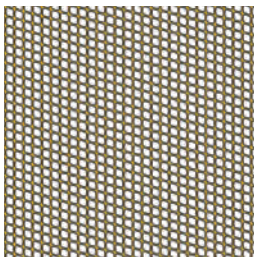
Implants

Mesh (all single packed)

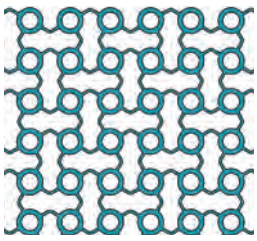
illustrated scale 2: 1



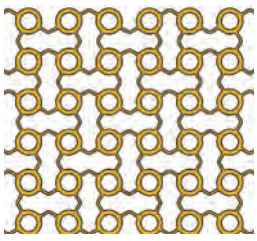
REF	Description
54-00262	Micro Mesh, 60 x 60 x 0.1 mm



54-00272	Micro Mesh, 60 x 60 x 0.2 mm



54-00344	Dynamic Mesh, 40 x 40 x 0.3 mm for 1.5/1.7 mm Screws
54-00345	Dynamic Mesh, 120 x 120 x 0.3 mm, for 1.5/1.7 mm Screws
54-00346	Dynamic Mesh, 90 x 90 x 0.3 mm for 1.5/1.7 mm Screws



54-00645	Dynamic Mesh, 120 x 120 x 0.6 mm, for 1.5/1.7 mm Screws
54-00646	Dynamic Mesh, 90 x 90 x 0.6 mm, for 1.5/1.7 mm Screws
54-00647	Dynamic Mesh, 200 x 200 x 0.6 mm for 1.5/1.7 mm Screws

Implant Storage

Implant Module

	REF	Description
	**29-15020**	Universal Neuro 2 Module (without Inlays)
	**29-15022**	Instrument Inlay Universal Neuro 2 Module, empty
	**29-15021**	Plate Inlay Universal Neuro 2 Module, empty
	**29-15300**	Disk Inlay Universal Neuro 2 Module, empty

Screw Disks

	REF	Description
	**29-15944**	Pre-Loaded Screw Disk, with 80 1.5 x 4mm Screws, Self-Drilling, non-sterile
	29-15945	Pre-Loaded Screw Disk, with 80 1.5 x 5 mm Screws, Self-Drilling, non-sterile
	29-15044	Pre-Loaded Screw Disk, with 80 1.5 x 4 mm Screws, Self-Tapping, non-sterile
	29-15045	Pre-Loaded Screw Disk, with 80 1.5 x 5 mm Screws, Self-Tapping, non-sterile
	29-15954	Screw Disk empty for 1.5 x 4 mm Self-Drilling Screws, non-sterile
	29-15955	Screw Disk empty for 1.5 x 5 mm Self-Drilling Screws, non-sterile
	29-15054	Screw Disk empty for 1.5 x 4 mm Self-Tapping Screws, non-sterile
	29-15055	Screw Disk empty for 1.5 x 5 mm Self-Tapping Screws, non-sterile

Ordering Information

Instruments

Drills (single packed, sterile)

	REF	Description
	91-12504	Drill 1.2 x 48 mm, working length 4 mm, Stryker-J-Notch
	91-12204	Drill 1.2 x 48 mm, working length 4 mm, Dental
	91-12304	Drill 1.2 x 85 mm, working length 4 mm, Stryker TPS
	91-12506	Drill 1.2 x 50 mm, working length 6 mm, Stryker-J-Notch
	91-12206	Drill 1.2 x 50 mm, working length 6 mm, Dental
	91-12306	Drill 1.2 x 87 mm, working length 6 mm, Stryker TPS

QuikDrive mini

	REF	Description
	**29-15030**	QuikDrive mini Sterilization Tray
	**62-50101**	QuikDrive mini Battery Powered Screwdriver
	**62-50113**	QuikDrive mini Battery Pack, sterile
	**62-50104** **62-50105**	Drill Adapter Dental Drill Adapter Stryker-J-Notch

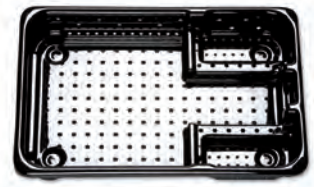
Instrumentation

	REF	Description
	**62-18110**	Universal Plate Forceps, 17.4 cm
	**36-00726**	Plate Bending Pliers with flat nose, 13.5 cm
	62-15020	Universal Neuro 2 Screwdriver Blade, 72 mm
	62-15024	Universal Neuro 2 Screwdriver Blade short, 42 mm
	**62-15001**	Universal Neuro 2 Screwdriver Handle
	**62-20295**	Universal Screwdriver Handle, rigid/rotating
	**64-00132**	Mesh Bending Pliers
	**62-18330**	In-Situ-Plate Cutter
	**62-40000**	NeuroClip Driver

Ordering Information

Implant Containers

Storage Container Full-Size

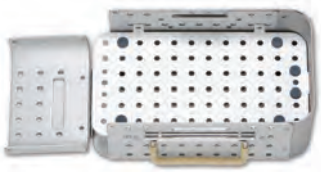


REF	Description
29-15026	Combined Tray
29-15023	Lid for Combined Tray
29-15027	Silicon mat for Combined Tray
29-15028	Instrument Inlay for Combined Tray

Storage Container Half-Size

REF	Description
29-15012	Universal Container, Half-Size, Two Layer, empty
29-15013	Lid for Half-Size Universal Neuro 2 Container

Storage Container Quarter-Size

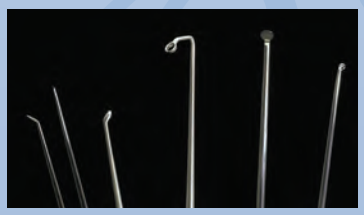


REF	Description
29-15031	Quarter-Size Container
29-15032	Lid for Quarter-Size Container
29-15008	Description Shield “Neuro System”

Instrumentation

REF	Description
29-15010	Universal Neuro 2 Instrument Tray, empty
29-15011	Lid for Universal Neuro 2 Instrument Tray

Complementary Products

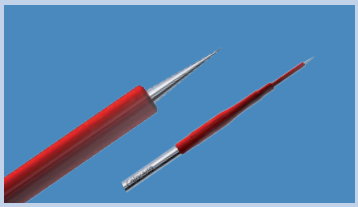


Leibinger Instrument Sets

Drawing on more than a century of experience in manufacturing high-quality surgical instruments, Leibinger instruments are made with high precision for neurosurgery.

Features

- Precision manufacturing process
- Easy handling
- Ergonomic design
- Superior balance
- Exceptional finish to exacting standards



Colorado MicroDissection Needle

Colorado MicroDissection Needles offer an ultra-sharp tungsten tip for precise soft-tissue dissection. These needles are available in a full selection of lengths and angles that provide versatility for procedural and surgeon preference.

Features

- Precise cutting and coagulation
- Exceptional hemostatic properties
- Highly polished tip

DuraMatrix-Onlay

DuraMatrix-Onlay is intended to be used as an onlay (non-sutured) dural substitute. It has excellent handling characteristics, is flexible and conforms to the contours of the brain. It is resorbable and is replaced by host tissue.

Features

- Conformable
- Highly Purified Type I Collagen from bovine Achilles tendon
- Balanced resorption
- Excellent handling characteristics

DuraMatrix

DuraMatrix is a conformable membrane matrix with balanced in vivo resorption of implant and replacement of host tissue. It has a thickness similar to native dura and has excellent handling characteristics.

Features

- Excellent handling characteristics
- Strong, conformable, watertight material
- Balanced resorption
- Highly Purified Type I Collagen from bovine Achilles tendon

HydroSet

HydroSet is an excellent osteoconductive hydroxyapatite bone substitute for a wide variety of clinical applications and surgical specialties.

Features

- Isothermic
- Remodels to bone through osteoclastic resorption
- Excellent wet field properties
- Easily implanted via injection or manual application

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