

Eva's rib.

On the potentials of craniomaxillofacial surgery*.

Legend tells us that woman was created from the rib of man. However we may view this story from the Book of Genesis, modern medicine offers applications pointing in this direction. Man sometimes functions as his own spare parts warehouse – such as for the transfer of muscle or fatty tissue to another part of the body or the use of bones as transplants. The body does not reject its own endogenic substances, and this is why autologous bone replacement is preferable to autogenous transplanting from one person to another or, for that matter, to xenogenic transfer from animals. However, bone also has the ability to form callus – the prerequisite for growing back together in the event of a fracture. This property is the basis of distraction, a method that has led to outstanding results in CMF surgery over the last 20 years, such as in the case of the girl we'll simply call Eva instead of her real name.

Sometimes a bone “forgets” to grow. Distraction “reminds” it of this.

Eva is four years old. Since her birth she had only half a mandible – a congenital deformity. The rest of the jaw was simply missing. Until now she could eat only mashed food, yogurt, soups and pureed food. Now four years old, something had to be done to eliminate the severe functional limitations with deglutition, mastication and speech. A barely 10 millimeter long piece was separated from the end of the existing jaw half and joined to a distractor for bone transport. The distractor is then activated day by day to move exactly one millimeter each day. In this way callus is generated in the narrow gap between the existing jaw half and the separated bone piece – soft, still pliable bone tissue that joins the two bone ends.



The method was first practiced by the Russian surgeon Gavril Ilizarov, who used it for the correction of bone fractures and severe deformities in the first half of the 20th century. The method was revolutionary – but remained unnoticed in the West until the collapse of the Eastern Bloc, following which distraction soon came to be widely accepted in craniomaxillofacial surgery. From the very beginning, KLS Martin was involved as a leading developer and

supplier of distractors, notably with regard to the second generation of distractors, initiated at the University Hospital of Zurich back in 1999. To this day, these distractors are still known as the “Zurich Design”. At the time KLS Martin showed that, thanks to its flat hierarchies, it is capable of acting fast – and it has done so on many occasions ever since. This is largely the achievement of a Development Division capable of filling special individual orders differing from the standard serial products within just a few days. In fact, the company clearly distinguishes itself not only by its flexibility in developing customized solutions, but also by its capacity to quickly take them to serial production as well. Needless to say, top quality is guaranteed consistently.

Genetically caused deformities are often the result of bones “forgetting” to grow. Distraction “reminds” the bone to grow and stimulates it to carry out the genetically stipulated “construction plan”. For this reason a single operation is usually sufficient, for example, for the pediatric treatment of craniosynostosis in order to open and distract the ossifying cranium to give the brain the room it requires for growth. Previously, premature ossification, which during a certain phase of childhood prevents the further growth of the cranium, could be treated only by an operation during which the middle part of the face was spontaneously brought forward by as much as 10 millimeters and fixed. Unfortunately, this entailed a very high risk of infection. Now, with distraction, children who once could not have been helped without an operation are hardly recognizable after completion of the distraction process. This gives children suffering from craniosynostosis the chance for a life worth living. And the relapse rate is extremely low.

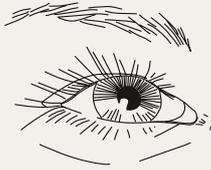
It's never only a question of restoring functionality – esthetics is just as important.

Here – as in nearly all cases of cranio-maxillofacial surgery – it is clear that this is not only a question of eliminating functional disturbances, but always an esthetic correction as well. As in the case of a young woman suffering from an extremely receding chin with the consequence that she was hardly able to close her mouth. Deglutition, speech and mastication were all made difficult. Here, it was not distraction alone, but a combination of distraction with classical titanium osteosynthesis that provided a visually and functionally perfect solution. The correction to the young woman's facial structure was made in two sessions. The maxilla was set back and fixed and, at the same time, the mandible was pulled forward by distraction. The receding chin was corrected upward by osteotomy and provided with a titanium Z-plate. The distractors were inserted during the first intervention and removed during the second intervention, which also included the chin correction. An elegant and patient-friendly solution – and also an esthetic one: because these two operations transformed the young patient into an attractive woman.

But what happens when it's not a matter of correcting congenital deformities, but a question of cranial injuries resulting in such swelling of the brain that it needs more room than the confines of the natural cranium? As in the case of a little boy where part of the cranial cap had to be removed during the neurosurgery required after an accident to allow the swelling of the brain to subside calmly. Here, distraction obviously is of no help. The problem is that the piece of the cranium removed cannot simply be put back in place later, because its removal causes necrosis of the edges of the bone covering. Previously, such regions had to remain open, at best with the makeshift protection of standard titanium mesh. Today, KLS Martin has a solution for injuries of this kind as well: a patient-specific solution.

Once again, this speaks for the flexibility of the company. Within only a few days, an exactly matched individual implant is manufactured, sterilized and shipped. There is even a special page available on our website just for this purpose, allowing CMF surgeons and neurosurgeons to describe their cases and upload the patient data. Within a very short time, a three-dimensional implant is manufactured on the basis of this CT data that matches the missing cranial geometry exactly. This is a much safer solution than a titanium implant adapted to the patient's needs by cold-working during the operation, since this could result in microcracks that endanger the long-term stability of the implant. An implant manufactured preoperatively according to CT data rules out such defects. And what's more: this simplifies and shortens the operation for both the surgeon and the patient.





The possibilities that this allows can be seen in cases in which the orbital floor is fractured. A strong shock can crumble the fragile bone as though it were a potato chip. It is then

impossible to join all the individual pieces together again. In order to stabilize the ocular bulb, a resorbable foil is inserted. However, depending on the extent of fracture, this does not always prevent a secondary reconstruction with a permanent implant. Otherwise, the eye would lose its support as soon as the resorbable implant dissolves. But how is the orbital floor reconstructed when it has fractured into countless bone fragments that can never be put together again? KLS Martin's Development Division has solved this problem by mirroring the CT data of the healthy orbital floor on the computer. On this basis, an exactly fitting implant can be manufactured that simply has to be inserted via a narrow incision below the eye and fixed during the operation.

KLS Martin is one of the few global suppliers capable of developing, manufacturing and delivering such implants in a very short time.

For adults, these implants are usually made of titanium, a material which the organism tolerates easily, or of polyether ether ketone (PEEK), a high-performance, biocompatible plastic that is very light, sterilizable and extremely stable – a material of the future. Such implants are fixed to the cranial bone as wafer thin, low-profile titanium plate designs, as offered as part of KLS Martin's ultra-low-profile Neuro System, so that the patient is hardly aware of the artificial implant. But in the case of the little boy, neither material is suitable. His cranium is still growing – inserting rigid implants would be out of the question. With poly-DL-lactic acid (PDLA), however, the situation is different. KLS Martin developed this unique poly-D- and L-lactide mixture in the 1990s to use it for resorbable implants. This material, which is completely absorbed in the body by hydrolysis, has now been used successfully for many years in craniomaxillofacial surgery and neurosurgery.

But its use on a large scale in the cranial cap is altogether new. This was made possible by inserting underneath a mixture of hydroxylapatite and tricalcium phosphate, a bone substitute material that ossifies to the same extent as the resorbable implant dissolves.

The challenge lies in setting standards – and then developing patient-specific solutions.



Thus, we found a solution for the little boy also – just as we did for Eva, the little girl with only half a mandible that distraction provided with the missing piece for which her joint cavity had been waiting for four years. But how is the now complete mandible joined to the mandibular joint? The surgeons decided in favor of a PEEK head designed to fit exactly to the joint cavity – only a temporary solution. Later, when the child has grown bigger and the PEEK joint head has become too small for the joint, it will be replaced – most probably with a piece of Eva's rib. ■

*It's the head that counts –
everything needed for CMF surgery.*

Millimeter by millimeter to success.

**Correcting malformations
by distraction.**

Page 10

The solution is in the dissolution.

**Resorbable implants
with SonicWeld Rx®.**

Page 11

Specifically for cranial interventions.

Plates, screws and meshes.

Page 13

Always a perfect fit.

**Patient-specific
implants.**

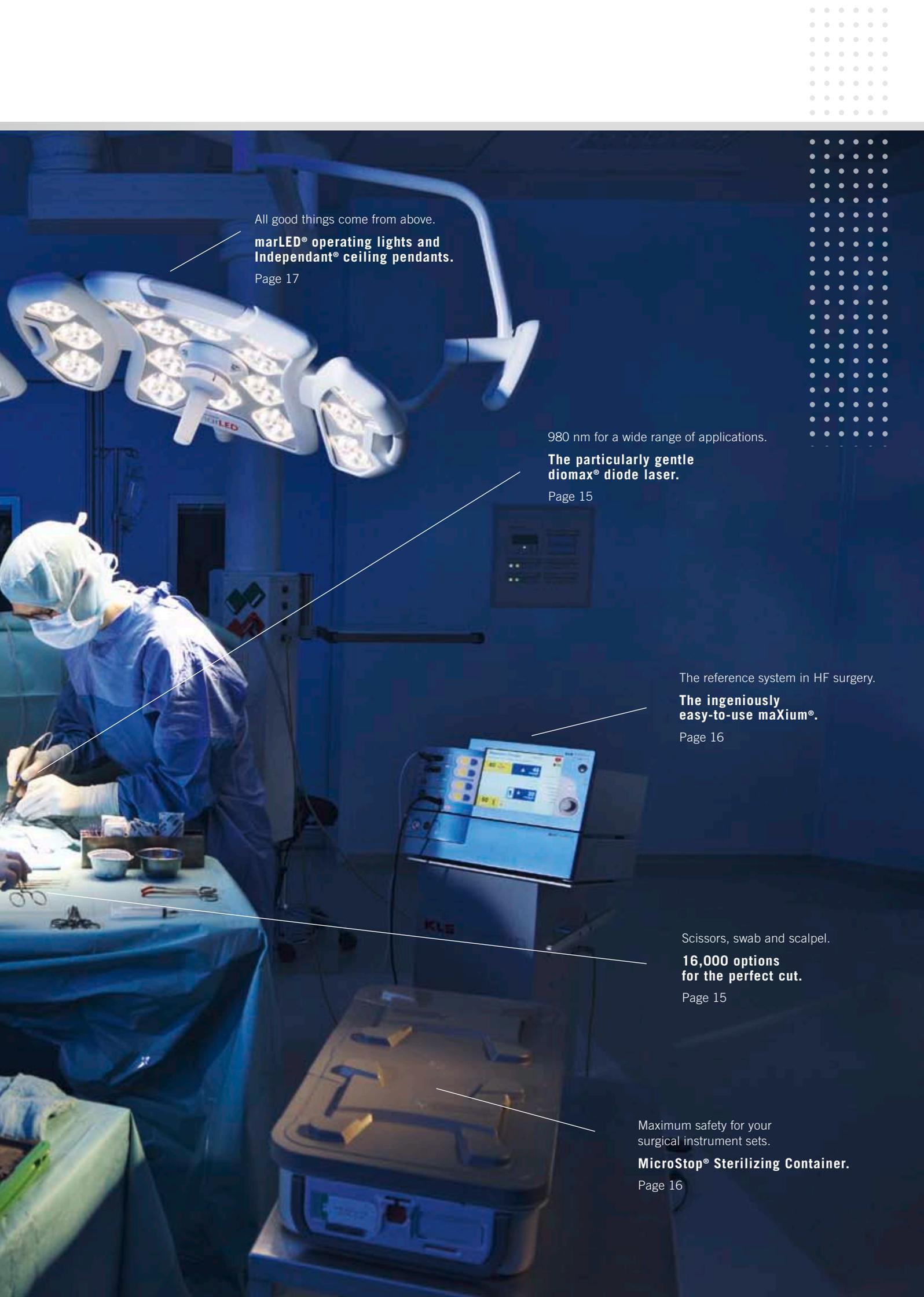
Page 14

Always the right item at hand.

**The innovative Level One
osteosynthesis system.**

Page 12





All good things come from above.
**marLED® operating lights and
Independent® ceiling pendants.**
Page 17

980 nm for a wide range of applications.

**The particularly gentle
diomax® diode laser.**

Page 15

The reference system in HF surgery.

**The ingeniously
easy-to-use maXium®.**

Page 16

Scissors, swab and scalpel.

**16,000 options
for the perfect cut.**

Page 15

Maximum safety for your
surgical instrument sets.

MicroStop® Sterilizing Container.

Page 16



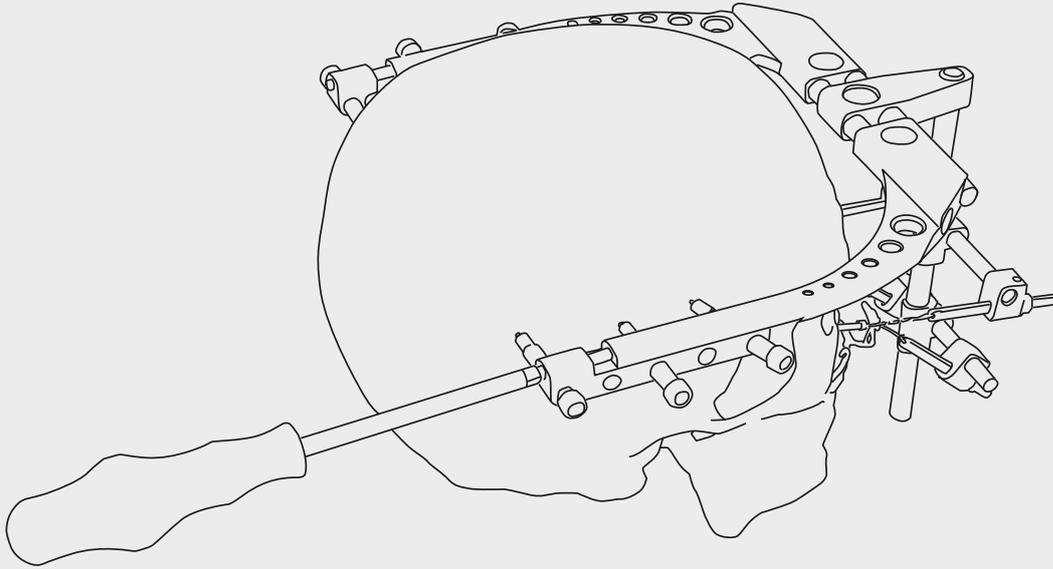
It's the head that counts – and the face. There is nothing with which we identify ourselves more than with the face. We are how we see ourselves. And more still: four of our five senses – sight, hearing, smell, and taste – are located in the head and the face.

The complete product portfolio –
for CMF surgery.

Severe craniomaxillofacial traumas or deformities can not only impair our senses, but often lead to psychosocial consequences as well: inasmuch as those afflicted cannot eat, taste, swallow or speak properly, they not only have to cope with functional impairment, but also feel frequently rejected by their social environment.

Craniomaxillofacial surgery offers procedures designed to correct such injuries and malformations, specifically by distraction and osteosynthesis. Distraction was invented by Gavril Ilizarov, who first used it in Russia after World War II. At the end of the eighties, the procedure became known in the West as well. In the meantime, distraction has matured into an indispensable pillar of CMF surgery – and KLS Martin is the global leader in this field.

This brochure gives you a succinct overview of everything needed for CMF operations – from plates, meshes, screws, pins, distractors and patient-specific implants all the way to lasers, HF generators, operating lights and pendant systems that supply all the needed media.

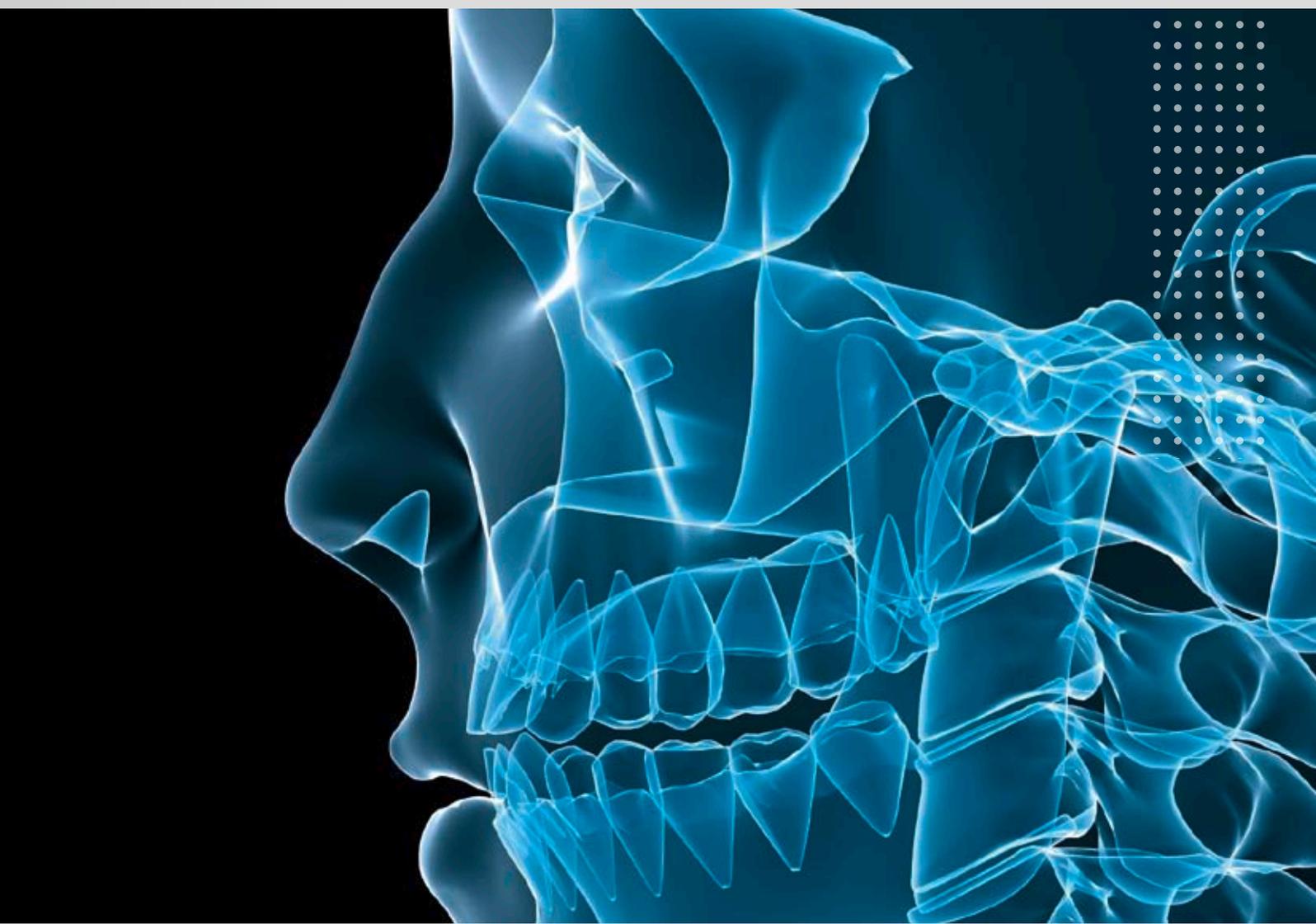


Millimeter by millimeter to success.

Correcting deformities by distraction.

KLS Martin offers internal mandibular distractors with the lowest profiles and – at the same time – the highest retention stability. Moreover, our extensive portfolio includes hundreds of other distractors for horizontal, transversal and vertical distraction, midface distraction, extraoral mandibular distraction, and much more.

In addition, KLS Martin excels with a prototyping capability that enables us to respond to requests for patient-specific models within just two weeks. After having already played an essential role in the development and manufacture of the “Zurich design” that is now used clinically all over the world with great success, prototyping again gives us the lead in the industry as a trailblazer and partner of CMF surgeons.



The solution is in the dissolution.

Resorbable implants with SonicWeld Rx®.

With SonicWeld Rx®, KLS Martin has developed a revolutionary technique for use in craniomaxillofacial osteosynthesis. It combines highly advanced ultrasound technology with resorbable implants to completely eliminate the need for a second operation. The procedure is simple: resorbable meshes are heated up, shaped to fit the application site and then fixed in place with SonicPins inserted into predrilled holes. This is done with a sonotrode that liquefies the pins, thus causing them to bond with the meshes and penetrate into the bone cavities to anchor themselves securely.

Both the meshes and the pins are made of a 100% amorphous poly-DL-lactic acid (PDLLA) – a completely biodegradable material. The method is clinically certified and validated and very patient-friendly as well. These implants degrade through natural hydrolysis in a controlled process. SonicWeld Rx® is primarily stable, convenient, fast, easy and safe. Designed for cranial fixation, ideal for pediatric trauma, and indicated also for cancellous bone structures.



The KLS Martin SonicWeld Rx® Solution is based on the BoneWelding® technology¹⁾ protected by the industrial property rights of WoodWelding AG, Switzerland, and has been licensed by this company.

¹⁾ "BoneWelding" is a registered Swiss trademark



Always the right item at hand.

The innovative Level One osteosynthesis system.

With Level One, KLS Martin offers the innovative storage system for use in osteosynthesis. It consists of basic modules, storage modules and color-coded screw clip magazines that can be filled individually and combined with each other as required.

Surgeons can always select among preconfigured storage modules or create their own systems if preferable. There is no limit to configuration options.

Level One – a smart concept without which osteosynthesis would be simply unthinkable. The application areas of Level One include:

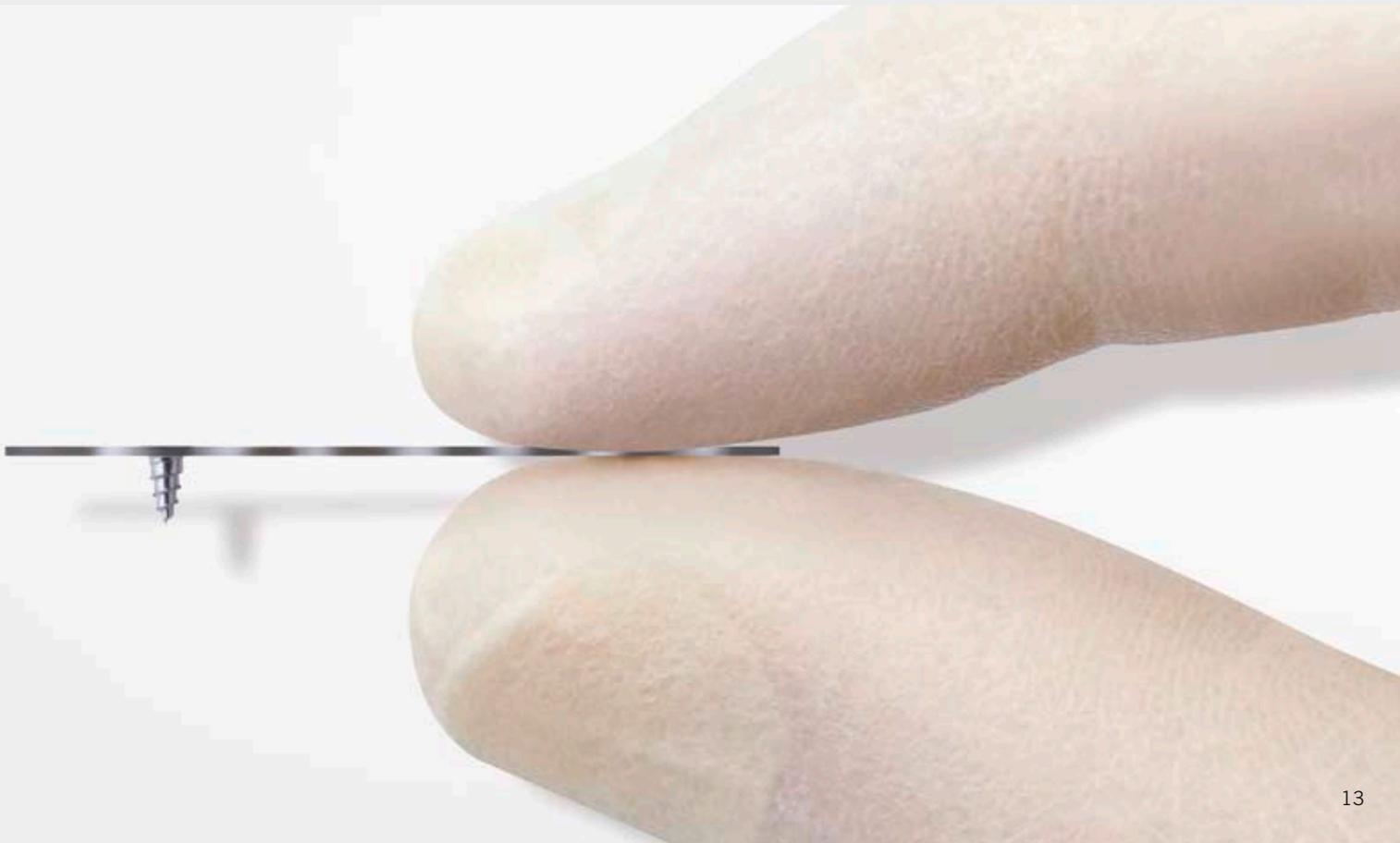
- Traumatology
- Orthognathia
- Craniofacial surgery
- Neurosurgery
- Mandibular reconstruction
- Skull base surgery
- Oculoplastic surgery



Specifically for cranial interventions.
Plates, screws and meshes.

The human skull is covered by a soft tissue layer that is very thin. Therefore, it is all the more important for neurosurgeons performing cranial surgery to have self-tapping and self-retaining screws with an extremely low profile, along with plates that allow fast and secure application. For patients, in turn, the essential point is that the plates, screws and meshes will not cause any inconvenience: that they wouldn't feel them – and that one cannot see them. KLS Martin's product portfolio satisfies both requirements – fast and secure application with just minimal palpability and cosmetic unobtrusiveness.

A comprehensive selection of different plate geometries allows the reconstruction of the most frequent cranial bone defects and fractures. It is ideal for fixing patient-specific implants in place as well. Traceability and identification are 100% guaranteed thanks to innovative tabs attached to each and every plate, without prejudice to the modularity that is at the core of the Level One philosophy. All screws are available in clip magazines that make charging, screw-picking and reordering an easy process. The product range is versatile, well-conceived and user-friendly.





Always a perfect fit.

Patient-specific implants.

Polyether ether ketone (PEEK), titanium mesh and solid titanium – these are the materials used for the patient-specific implants offered by KLS Martin. PEEK is an innovative, biocompatible high-performance plastic – elastic, low-weight, yet very strong and thermostable. Thanks to its physical properties, PEEK is very similar to cortical bone.

Titanium, in contrast, offers second-to-none biocompatibility. Titanium implants are also designed and manufactured to fit each patient's needs. They come either in mesh form or as solid, high-strength versions used in reconstruction.

KLS Martin belongs to the select global circle of just a few suppliers that are capable of making such patient-specific implants and delivering them on short notice. The associated procedure is extremely user-friendly: surgeons simply upload their patient-specific data via the online portal of the KLS Martin website and KLS Martin takes care of the rest: processing the data, manufacturing the implants and dispatching them in the shortest possible time.

But our services include more than patient-specific implants. The following web page also allows you to request anatomical models to optimize preoperative planning: www.klsmartin.com/psi



Scissors, swab and scalpel.

16,000 options for the perfect cut.

No operation without instruments – it's good to know that KLS Martin offers more than 16,000 such articles that meet the highest user demands plus the toughest current legal requirements in the European Union, the USA, Japan and many other countries.

From design and selection of raw and other materials all the way to manufacturing, hardening, tempering and surface finishing, the most stringent quality criteria are in place and meticulously observed at KLS Martin. All products are finally subjected to careful inspection and testing. And since we are absolutely convinced of the excellent quality of our surgical instruments, we back them with a lifetime warranty.



Particularly gentle.

The diomax® diode laser.

Excellent absorption, short pulse times and a wide range of applications – these are the hallmarks of our diomax® diode laser. The versatility is explained by the wavelength of 980 nm and a pulse time of just 5 ms. It is therefore no longer surprising that this very gentle laser can be used in almost any surgical field.

Craniofacial surgery is an ideal field for the diomax® diode laser to display all its strengths – whether in soft tissue surgery or in the transcutaneous and interstitial treatment of hemangiomas. As a maintenance-free substitute of the classic Nd:YAG laser, the diomax® diode laser is a no less effective therapeutic option for adenomas, fibromas, condylomas and other soft tissue lesions than its predecessor. Other special applications include vestibuloplasty and temporomandibular joint arthroscopy.

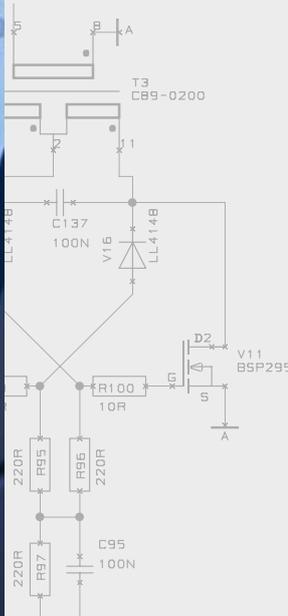


The reference system in HF surgery.

The ingeniously easy-to-use maXium®.

The maXium® sets standards in terms of safety, ergonomics, simplicity, speed, precision and versatility. Thanks to its “Quick Step” control and clearly structured maxi-display, handling is absolutely intuitive, making things as easy as possible for users.

Bipolar coagulation is the method of choice in craniofacial surgery. Special NON-STICK forceps are available that set standards with their adhesion-preventing properties. A range of different types of currents – with and without auto-start function, with optional activation by foot switch or handle push-buttons, and with two bipolar outputs – leave nothing to wish for.



Maximum safety for your surgical instrument sets.
MicroStop® Sterilizing Containers.

Large, medium, small – and there is the mini-set for good measure. As you would expect, all of them comply with the national and international requirements and standards for packaging systems. And they feature a revolutionary sterile barrier that makes costly single-use filters a thing of the past, once and for all: the MicroStop® Sterilizing Containers from KLS Martin. These sterilizing containers, available now in the second generation, excel with a separation efficiency of 99.99997%, as tested and certified by the Fraunhofer Institute for Interfacial Engineering and Biotechnology. Thanks to the Greencheck® safety system, users can check at a glance whether the container has been properly sterilized or opened already. All containers are perfectly matched to each other for optimal space utilization in the sterilizer and during subsequent storage. You couldn't handle your surgical instruments more efficiently to have them ready for use for the next successful operation.



MicroStop® Sterilizing Container – certified according to:

- ISO 11607 Part 1 and Part 2:2006, EN 868 Part 8:1999, DIN 58953 Part 9:2002
- CE-marking acc. to EU Directive 93/42/EEC (MDD)
- Approved for steam sterilization procedures acc. to EN 285:2006 + A1:2008 and validated acc. to ISO 17665 Part 1:2006



All good things come from above.
marLED® and Independant®.



reddot design award
winner 2008



True, operating lights using LEDs as light sources are not a rarity – but marLED® is different. KLS Martin offers you a light system that is not only smaller and more compact, but more efficient in light yield and less costly in its power requirements as well. Most importantly, however, marLED® offers a unique light quality thanks to the special mixing process taking place right inside the LED “engines”. This effectively eliminates any unwelcome color shadow casting. Another unrivaled feature is the light field adaptation function enabling surgeons to use an oval or circular light field for best illumination of the operating site. Color temperature is variable too, as you can choose between day-light quality and warm-white artificial light. And to round it all off, we are proud to say that marLED® has won prestigious, internationally recognized awards for its outstanding design.

But with KLS Martin, it is not just the light that counts among the good things coming from above. The Independant® pendant system, a modular ceiling-mounting supply and suspension system, offers variable multi-function service heads with gas, electricity and media connections, plus adequately sized installation platforms and supports for HF units, laser systems and TFT flat screen monitors. Infusion stands can be optionally integrated as well. All KLS Martin ceiling pendants are available as customized versions to fit in just perfectly. Not surprisingly, these systems have become very popular in many fields – surgery, endoscopy, anesthesia, intensive care medicine and as monitor supports. Independant® systems carry loads from 30 kg to up to 1,000 kg, save you space and provide for flexible positioning of any equipment required in state-of-the-art operating rooms.





A truly impressive product portfolio.

**Backed by a speed of response
not easily found elsewhere.**

KLS Martin offers you almost everything you need for successful operations: from indispensable instrument sets and specific solutions all the way to peripheral equipment needed in any operating room. What makes the difference in the final instance, however, is the flexibility on which you can rely. KLS Martin is always ready to seek new solutions in close collaboration with surgeons – and to explore new paths without hesitation. We have a record to back this statement. Take the development of resorbable implants – when our experts began to

work with biodegradable materials under clean-room conditions. Or take the osteosynthesis revolution – where the company showed the same degree of commitment and determination to deliver results in close collaboration with Prof. Champy and the SORG founders. This entrepreneurial spirit still drives KLS Martin today – as evidenced by our patient-specific implants. We are looking forward to pushing the limits still further in an ongoing effort to explore new medical territory. Who knows, perhaps with you anytime soon?

*We are looking forward to the challenges
ahead of us.*

Karl Leibinger GmbH & Co. KG
78570 Mühlheim · Germany
Tel. +49 7463 838-0
info@klsmartin.com

KLS Martin GmbH + Co. KG
79224 Umkirch · Germany
Tel. +49 7665 9802-0
info@klsmartin.com

Stuckenbrock Medizintechnik GmbH
78532 Tuttlingen · Germany
Tel. +49 7461 16 58 80
verwaltung@stuckenbrock.de

Rudolf Buck GmbH
78570 Mühlheim · Germany
Tel. +49 7463 99 516-30
info@klsmartin.com

KLS Martin France SARL
68000 Colmar · France
Tel. +33 3 8921 6601
france@klsmartin.com

Martin Italia S.r.l.
20059 Vimercate (MB) · Italy
Tel. +39 039 60 56 731
italia@klsmartin.com

Martin Nederland/Marned B.V.
1270 AG Huizen · The Netherlands
Tel. +31 35 523 45 38
nederland@klsmartin.com

KLS Martin UK Ltd.
Reading RG1 3EU · United Kingdom
Tel. +44 1189 000 570
uk@klsmartin.com

Nippon Martin K.K.
Osaka 541-0046 · Japan
Tel. +81 662 28 90 75
nippon@klsmartin.com

KLS Martin L.P.
Jacksonville, FL 32246 · USA
Tel. +1 904 641 77 46
usa@klsmartin.com

Gebrüder Martin GmbH & Co. KG
Representative Office
121471 Moscow · Russia
Tel. +7 499 792-76-19
russia@klsmartin.com

Gebrüder Martin GmbH & Co. KG
Representative Office
201203 Shanghai · China
Tel. +86 21 2898 6611
china@klsmartin.com

Gebrüder Martin GmbH & Co. KG
Representative Office
Dubai · United Arab Emirates
Tel. +971 4 454 16 55
middleeast@klsmartin.com

Gebrüder Martin GmbH & Co. KG
A company of the KLS Martin Group
Ludwigstaler Str. 132 · 78532 Tuttlingen · Germany
Postfach 60 · 78501 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax 706-193
info@klsmartin.com · www.klsmartin.com

