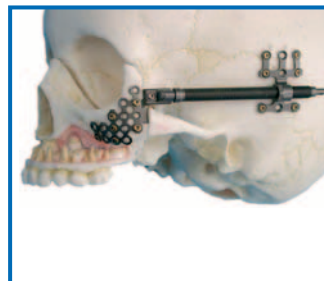
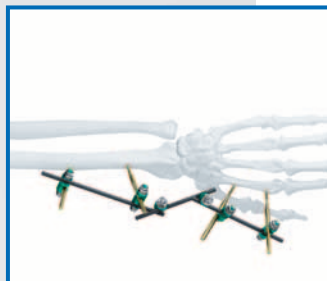
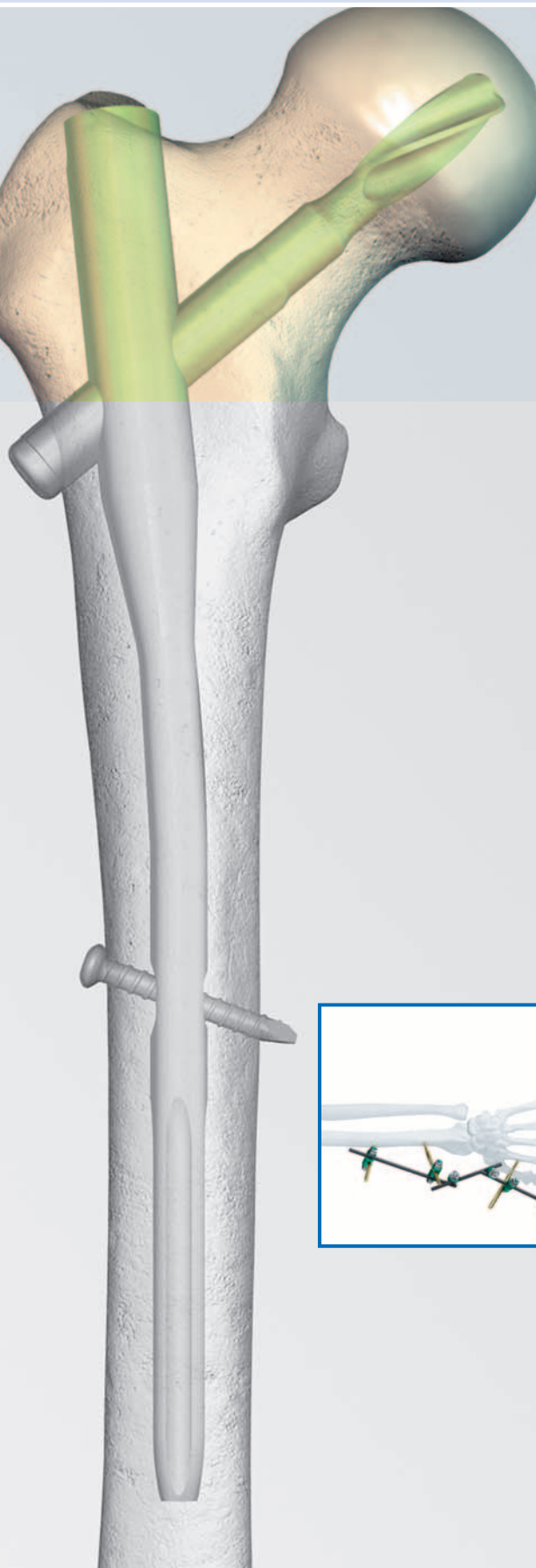


## New Products from AO Development



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Dear reader,

After the successful introduction of the LCP, the AO Foundation has turned its focus on a new nail generation. Recently, we have introduced several new nailing systems. In this issue, you will read about the new Proximal Femur Nail Antirotational (PFNA) which combines the benefits and the technique of the successful PFN with a single blade element which has a high cut-out resistance, and provides rotational stability. The new Ti Cannulated Humeral Nail will replace the well-known UHN. The Modular Aiming Device enables distal and proximal locking for intramedullary nail systems without the need for an image intensifier. Soon the AO will introduce the Expert Tibia Nail, the Expert Nail for retrograde/antegrade femoral nailing and the Reamer Irrigator Aspirator System (RIA).

The new Small External Fixator completes the external fixator family which now provides for the whole body.

For patients suffering from the Thoracic Insufficiency Syndrome (TIS), the Vertical Expandable Prosthetic Titanium Rib (VEPTR) provides you with a treatment for these rare rib anomalies associated with scoliosis for which no cure has been available until today. The VEPTR mechanically stabilizes and distracts the thorax without fusion in seriously ill, juvenile patients. It stabilizes the pulmonary condition caused by musculoskeletal deformity and allows the continued growth of the thoracic cavity and spine.

In craniomaxillofacial surgery, pediatric patients suffering from cranio-synostosis can now be treated with the Rapid Resorbable Fixation System which makes use of a faster-resorbing polymer.

Also in the fields of biomaterials, results of a prospective multi-center study with chronOS Inject, an injectable and resorbable bone void filler are being presented.

All these new technologies have been developed in an organization of medical-technical committees, the so called TK-System. It offers a forum to surgeons worldwide to share their clinical experience and to develop new treatment options. An article will introduce the TK-System to you on the occasion of a reform which provides more autonomy to the different specialties and increases the involvement of surgeons from Asia and Latin America. Latin America is also the home of a surgeon featured in the Portrait column for his innovative ideas in external fixation, Col Carlos Satizábal, MD, from Bogotá, Colombia.

Once again, I would like to stress that none of the product descriptions in this publication are a substitute for the AO's surgical techniques or the AO teaching tools. You can obtain more detailed information on these products from the AO or your local SYNTHES® representative.

If you have any comments or questions on the articles or new products, please don't hesitate to contact me.

Yours faithfully,

Norbert P Haas

Norbert P Haas

## DEVELOPMENT OF NEW IMPLANTS WITHIN THE AO FOUNDATION

**The AO Foundation develops new surgical techniques, implants, and instruments under the medical guidance of independent surgeons. Responsible for the development and clinical testing of these devices as well as their educational concepts is an organization of medical-technical committees—the TK-System. It consists of Technical Commissions and Specialty Expert Groups in which around 100 surgeons work on the solution of clinical problems.**

The AO Foundation offers a platform to surgeons worldwide to share their clinical experience and develop new treatment options, the TK-System. The TK-System is structured according to the specialties general trauma, spine, and craniomaxillofacial. Each section consists of several Expert Groups (EG) for specific anatomical regions and a Technical Commission (AOTK). Members of these committees are surgeons who are known specialists in the relevant field and highly qualified engineers from the AO Development Institute (ADI) and Synthes, Inc. The AO Research Institute (ARI) shares its expertise by answering research related questions or informing about latest findings.

The TK-System is lead by an Executive Board which ensures common standards and provides overall strategic guidance in overlapping areas relevant to all three specialties general trauma, spine, and craniomaxillofacial.

The Specialty Expert Groups are an open forum for ideas concerning relevant clinical problems and possible solutions. After identifying medical needs and defining critical characteristics, the engineers work on technical solutions and present them to the group. These devices are discussed, adapted, and tested (material, mechanical, and biomechanical) until a final prototype is adequate for a clinical handling documentation series

or animal tests. This process lasts until the responsible EG proposes the development to their Technical Commission (AOTK) for final approval. Only the relevant AOTK can release products to the market, providing an additional quality assurance check. It is worth mentioning that all legal obligations as CE mark or FDA approval have been obtained long before the AOTK decision about market release, implying that AO quality standards are higher than any existing legal requirements worldwide.

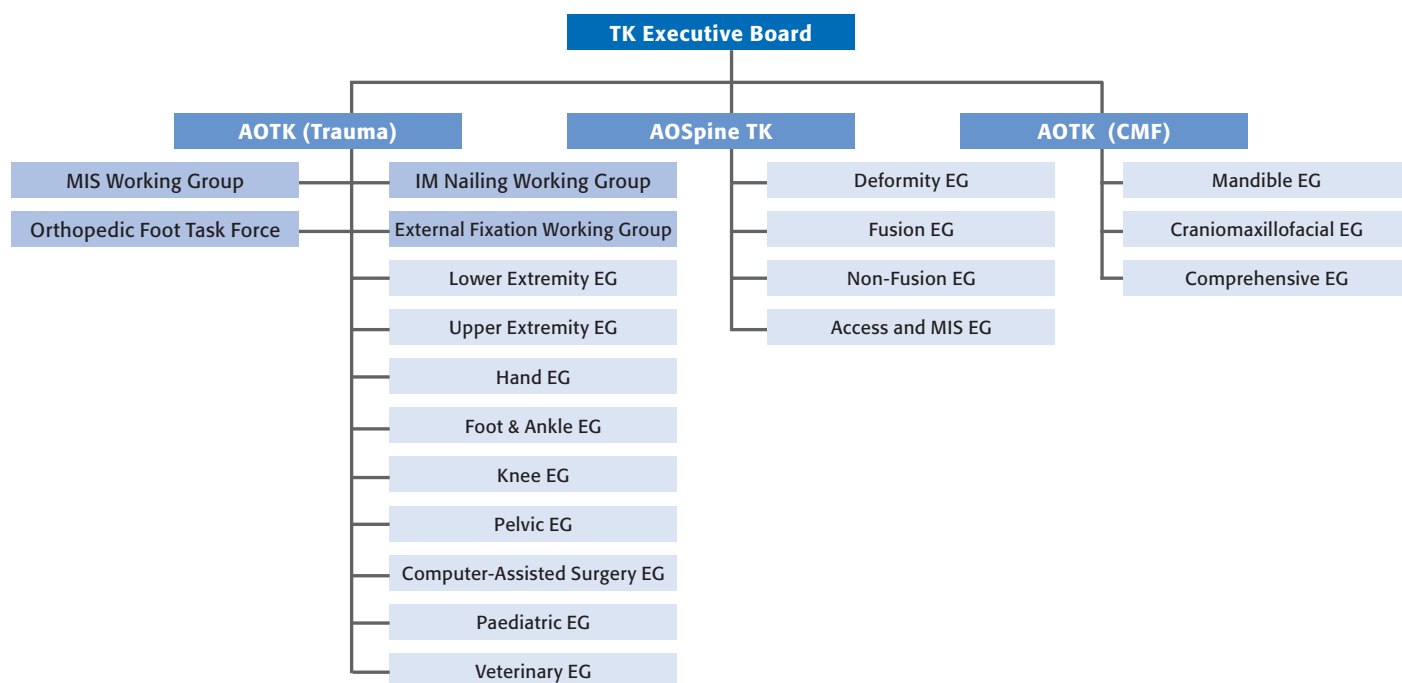
Depending on the complexity of the product, teaching concepts and materials (videos, publications, course contents etc.) are defined and its production controlled by the EG which was responsible during the development process. The medical content of all publications from the AO on these products is supervised by the relevant EG.

As in all boards of the AO Foundation, the medical members hold the majority in all committees of the TK-System. The independent surgeons ensure decision making according to clinical necessities.

The TK-System is open to input from surgeons worldwide. In the past, surgeons from Europe and North America dominated, but lately representation from Latin America and Asia has increased dramatically. Special regional exchange meetings with AO East Asia and AO Latin America were held in 2004.

### Realizing an idea with the AO Foundation

Any surgeon can address his approach for solving a clinical problem to the AO. After a first assessment, contact will be established to other innovative AO surgeons organized in the relevant Expert Group. In collaboration with them, the potential of the technique, possible improvements, and alternative approaches will be evaluated. At the end of this discussion, a decision is made as to whether a project can be started.



If the project is accepted, the surgeon who proposed the idea will be involved in all further activities such as the evaluation of prototypes, testing and later teaching.

The development and testing process continues until the responsible Expert Group judges that the new solution is an improvement on the existing surgical techniques. Then a CE-mark/FDA approval will be obtained, allowing the start of clinical testing. These trials take place in selected clinics to optimize the clinical performance. Finally, the then thoroughly tested product is forwarded to the AO Technical Commission for final approval and global release as an AO recommended treatment procedure.

Parallel to the clinical testing, the production of teaching concepts and materials, eg, teaching videos, is started in collaboration with AO International. AO Courses ensure proper training for the users of the new product. The performance of the new product is followed up and evaluated. User meetings are held to exchange experience and further improve the technology or handling.

For details please check: [www.aofoundation.org/fromideatoproduct](http://www.aofoundation.org/fromideatoproduct)

### Summary

The TK-System of the AO Foundation offers any surgeon worldwide an opportunity to realize his ideas. Innovative surgeons are provided with

optimal technical support, and introduced to an international network of surgeons dedicated to research, development, clinical testing, and teaching. As part of this clinical think tank they will support the efforts of the AO Foundation to provide the surgical community with continuously improved treatment options for the benefit of the patient.



**Ted Hansen, Chairman of the orthopedic foot group.**



Dean Lorich, Dankward Höntzsch, Christian Krettek, Norbert Südkamp

## NEW UPPER EXTREMITY PRODUCTS

### Ti Cannulated Humeral Nail

The Ti Cannulated Humeral Nail is indicated for fractures of the proximal humerus, humeral shaft, malunions/nonunions, and impending pathologic fractures.

It has a universal design for the right or left humerus, and for antegrade or retrograde insertion.

The Cannulated Humeral Nail can be inserted in an antegrade or retrograde approach and includes spiral blade, standard, and compression locking options. The distal locking holes on the Cannulated Humeral Nail are angled for stable, multiplanar fixation.

The nail is available in 7.0 mm, 9.0 mm, and 11.0 mm shaft diameters with proximal ends of 7.0 mm, 9.0 mm, and 11.0 mm, respectively. Lengths will be offered from 190 mm to 320 mm in 10 mm increments.

The locking options include spiral blade locking (using the current Spiral Blade for Humeral Nail), standard locking (with 4.0 mm locking screws), and compression locking. A 5° bend is located 55.0 mm from the proximal end, allowing an off-axis entry site to minimize damage to the articular surface. Distal locking holes on the Cannulated Humeral Nails are angled 45° from each other for stable, multiplanar fixation anterolaterally and/or anteromedially, and to reduce the possibility of skiving on the lateral supracondylar ridge. The use of both distal holes will minimize toggle of the nail's distal end. A locking end cap is included in the system to secure the spiral blade in the proximal nail slot, creating an angular stable construct.

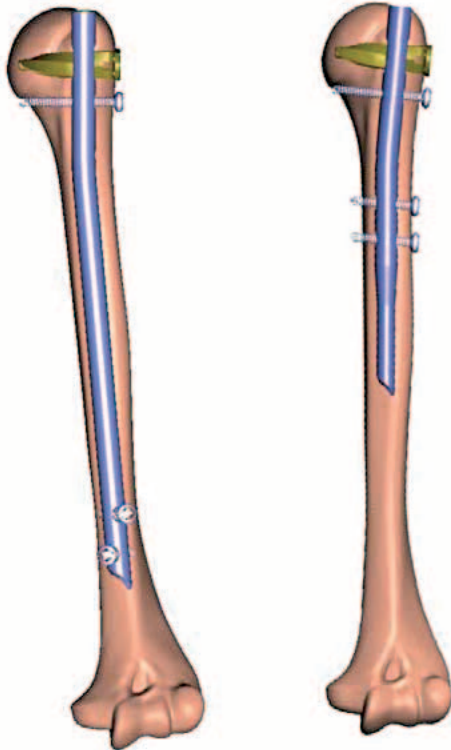
The Ti Cannulated Humeral Nail uses newly designed instrumentation and new 4.0 mm Titanium Locking Screws with a T25 StarDrive recess.

### Modular Aiming Device (ModAD)

Intramedullary locked nailing of the tibia, femur, and humerus is a technically demanding procedure. To achieve distal locking accurately, in the least possible time, and with the least possible exposure to radiation is a major concern with the free-hand technique. The Modular Aiming Device (ModAD) enables distal and proximal locking for most common Synthes Titanium Intramedullary Nail Systems without the need for an image intensifier.

It has been recognized that some deformation of locked intramedullary nails is inevitable as they are inserted, and that, therefore, a simple aiming arm, mounted on the proximal end of the nail alone, will not sufficiently provide accurate distal aiming. To compensate for insertional implant deformation, a proximally mounted radiation independent aiming device was developed. The ModAD System covers UHN, UFN/CFN and UTN/CTN (in TAN and stainless steel) and will be provided modular.

The handling of the ModAD is similar to the existing Distal Aiming Device (DAD) for UTN which will be replaced by the ModAD.





### Distal Humerus Plate (DHP)

Treatment of distal humeral fractures using the standard reconstruction plates has shown to be difficult and may lead to poor results in osteoporotic bone and in very distal fractures, where the LC-DCP or standard reconstruction plates do not provide sufficient stability.

The Distal Humerus Plate (DHP) was developed to allow treatment of difficult fractures, allowing fixation of bone very distally, and increasing the number of fixation possibilities which provide high stability of fixation with less risk of loss of reduction and allow early functional mobilization.

The DHP is indicated for intraarticular fractures of the distal humerus, supracondylar fractures of the distal humerus, and nonunions of the distal humerus.

The DHP systems consist of dorsolateral plates, with or without support, right and left, with 3, 5, 7, 9, or 14 holes and medial plates, right and left with 3, 5, 7, 9, or 14 holes, to fit all different fracture patterns and fracture extensions.

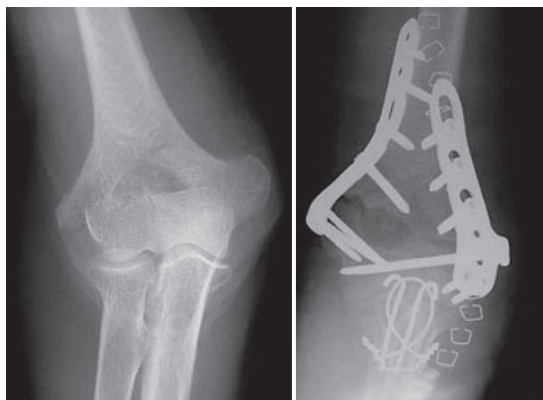
The DHP is available in stainless steel and titanium.

On the medial plate the distal screws are directed from the epicondyle to the trochlea.

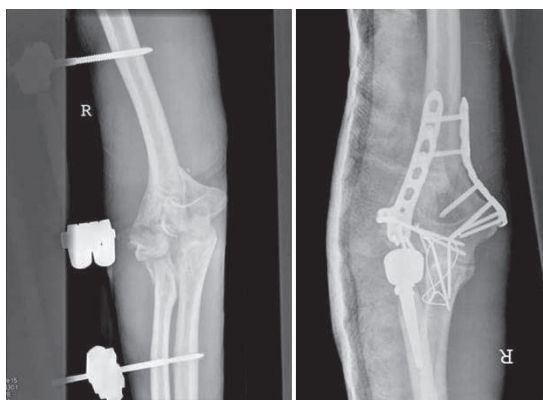
On the dorsolateral plate the distal screws are directed to the capitellum. In addition the screws of the lateral support are inserted through the capitellum. The screw is designed for least interference with other screws, the insertion is done through an aiming device which also provides the necessary interfragmental compression if needed.

The distal part of a dorsolateral or medial plate has threaded holes which accommodate either locking head screws 2.7 mm (head LCP 2.4) or standard cortex 2.4 mm screws.

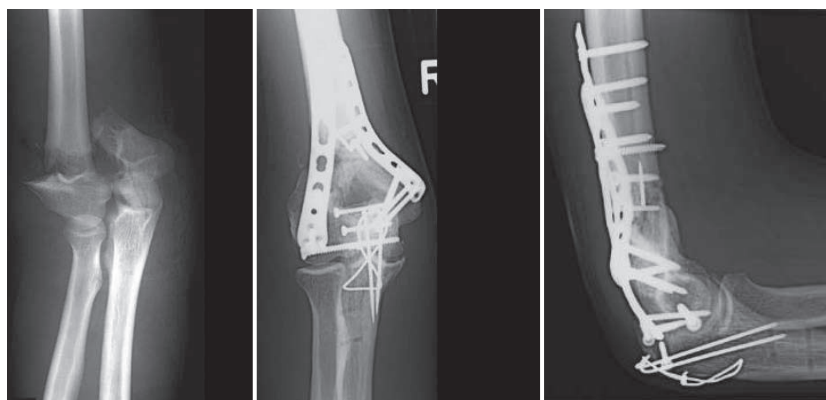
The shafts of the plates have LCP combi-holes designed to be used either with 3.5 mm locking head screws or with standard cortex screws 3.5 mm.



85-year-old woman, 13-C3, low supracondylar fracture.



40-year-old man, 13-C3 fracture.



23-year-old man, 13-C3 fracture.

Dankward Höntzsch

## EXTERNAL FIXATOR FAMILY



### Small External Fixator

The new Small External Fixator is a major upgrade of the current system in terms of handling, functionality as well as patient comfort, and is mainly used for the treatment of distal radial fractures. The latter represent the most common fracture type with a frequency of about 25%. Extension fractures, also well known as Colles' fractures, figure with an occurrence rate of about 90% among the distal radial fractures.

Internal fixation using an external fixator is performed in about 15% of all forearm fractures treated operatively. This type of osteosynthesis is employed primarily for 23-C and, to a lesser extent, also for 23-A2 and 23-A3 fractures.

The new Small External Fixator allows for wrist spanning and convenient non-spanning external fixation which enables early wrist mobilization.

A new generation of clamps offers simplified handling, which shortens the operating time. This clip-on, self-holding clamp enables rod-to-rod, rod-to-Schanz screw, and rod-to-K-wire connections. The function of the rod-to-rod connection is new for a clip-on, self-holding clamp. Until now, a combination clamp had to be used for this function. This clamp used with the curved carbon-fiber rod, is suitable for non-spanning wrist fixation. The clip-on, self-holding clamp has an overall length of 33 mm and a maximum diameter of 10.5 mm.

### Hydroxyapatite Coated Schanz Screw

Loosening of external fixation Schanz screws can lead to an increased risk of pin tract infection. As the length of time a Schanz screw is in place increases, so does the risk of loosening. Loosening is also more probable in both cancellous and osteopenic bone, where the purchase of the Schanz screw is not as secure as in cortical bone.

Hydroxyapatite coatings have been shown to improve the integrity of the bone-pin interface and thereby reduce loosening. It is made up of calcium, phosphate, and hydroxide, and, when used as a coating, provides excellent biocompatibility at the bone-implant interface. It increases osteointegration by allowing the bone to "grow" into the coating. This characteristic proves especially valuable in cases where external fixation devices are applied for long periods and/or where there is poor quality of bone.

The coated screws are available for small, medium, and large external fixator systems in different lengths, stainless steel or titanium, self-drilling or standard, and all packaged sterile.



Jesse Jupiter

## NEW HAND PRODUCTS

### 2.4 mm Cannulated Screw System

A clinical need exists for a tiny, cannulated screw for fixation of fractures and nonunions of small bones, and small bone arthrodeses. The 2.4 mm Cannulated Screw provides an alternative for the same indications as the 3.0 mm Cannulated Screw, but it can also be used for fractures in smaller bones of the hands and feet. The primary usage of these screws will be as independent lag screws in small bones for hand and foot surgery. Furthermore, the use of these small screws avoids excessive bone removal when implanting, solving the clinical issue of excessive bone removal in small bones.

The 2.4 mm Cannulated Screw System is the smallest cannulated screw offered for small bone indications in the hand and foot. The system features 2.4 mm Cannulated Screws ranging from 10.0 mm to 30.0 mm long and is offered in short and long threads. A 0.8 mm guide wire and related instrumentation allows for precise placement of the screw. The screw system complements existing cannulated screw systems by providing a smaller option



than 3.0 mm for small bone fractures. The system addresses needs that were previously unmet by the larger screws.

The 2.4 mm Cannulated Screw Set features mini-cannulated screws made in stainless steel, and their related insertion instruments. Long thread screws range from 10–20 mm in 1.0 mm increments and 22–30 mm in 2.0 mm increments. Short thread screws range from 17–20 mm in 1.0 mm increments and 22–30 mm in 2.0 mm increments. The screws are self-drilling and self-tapping and have a StarDrive head that allows for self-retention and improved torque transmission.

The system is housed in a module that fits in the Modular Hand System or Modular Foot Sets.



34-year-old patient, radial styloid fracture, good bone quality, 1.2 mm screw used.

- a Preoperative x-ray.
- b Follow-up after 1 week, AP view.
- c Follow-up after 1 week, lateral view.
- d Follow-up after 1 week, oblique view.
- e Follow-up after 4 weeks, AP view.
- f Follow-up after 4 weeks, lateral view.
- g Follow-up after 4 weeks, oblique view.

Phil Kregor, Keith Mayo, Chris van der Werken

## NEW LOWER EXTREMITY PRODUCTS

47-year-old female, slipped and fell down the stairs. Traumatic, single fracture 31-A2.1.

- a Preop x-ray.
- b Postop x-ray.
- c Postop x-ray after 5 weeks.
- d Postop x-ray after 6 months.



### Proximal Femur Nail Antirotation (PFNA)

The PFNA will replace the Proximal Femoral Nail System (PFN) which was developed in 1997 for the treatment of (per)trochanteric fractures. The original PFN allowed fracture stabilization with a load bearing sliding screw and with an additional hip pin for rotational stability of the head-neck fragment.

The new PFNA System with the unique spiral blade has a comparable rotational stability as the PFN. This is achieved by compaction of the cancellous bone around the surface of the PFNA blade and results in an excellent fit between the blade and (generally osteoporotic) bone.

Current clinical experience proves that the overall complication rate, especially the cut out rate, is low.

The main features of the PFNA system are described as follows:

#### PFNA (indications)

- Petrochanteric fractures (31-A1 und 31-A2)
- Intertrochanteric fractures (31-A3)
- High subtrochanteric fractures

#### PFNA long (indications)

- Low and extended subtrochanteric fractures
- Ipsilateral trochanteric and femur shaft fractures
- Pathological fractures

#### PFNA blade

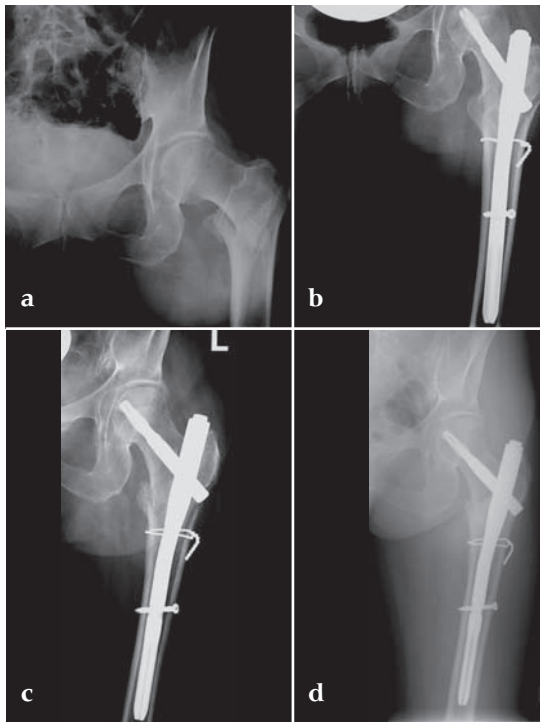
- Rotational and angular stability achieved with one single element.
- Compaction of cancellous bone for good anchoring of the blade, which is especially important in osteoporotic bone.
- All surgical steps required to insert and lock the blade are done through one lateral incision, which simplifies blade exchange or removal.

#### PFNA nail

- The PFN design has been proven more than 200,000 times and guarantees an optimal fit of the nail in the femur.
- The medial-lateral angle of 6° allows insertion at the tip of the greater trochanter.
- The PFNA instrumentation offers the possibility of static or dynamic locking for standard and small size nails.
- The flexible nail tip eases insertion and avoids stress concentration distally.

### Periprosthetic Locking Head Screw with StarDrive

The new Periprosthetic Locking Head Screws are intended for monocortical use with LCP/LISS for the fixation of fractures when an intramedullary component is in place. Otherwise, they have the same indications as the existing screws. They have a blunt-nose tip to allow bony contact with more screw threads. The new screws have a diameter of 5.0 mm and come in shorter lengths of 8, 10, and 12 mm. They are available in stainless steel and titanium (TAN).





### LCP Proximal Femur 4.5

The LCP Proximal Femur 4.5 is part of the Locking Periarticular Plating System, which merges locking head screw (LHS) technology with conventional plating techniques.

It is indicated for pertrochanteric fractures, subtrochanteric fractures, instable intertrochanteric fractures, and intertrochanteric fractures with reverse obliques, as well as malunions and nonunions of these fracture types.

The LCP Proximal Femur 4.5 is a stainless steel plate with a limited contact profile. The proximal portion of the plate is anatomically contoured to approximate the lateral profile of the proximal femur. Therefore, it comes in a right and left version.

The two proximal screw holes accept 7.3 mm cannulated locking and 7.3 mm cannulated conical screws. The third locking hole accepts a 5.0 mm cannulated LHS and is angled to converge at the tip of the proximal 7.3 mm screw and is intended to resist varus deformity forces. The remaining screw holes are locking compression plate (LCP) holes which combine a dynamic compression unit (DCU) hole with a locking hole. This provides the surgeon with the flexibility to gain axial compression and angular stability throughout the length of the plate. Because of the proximal screw configuration, the plate can be compressed with the articulated tension device to create a load sharing construct. This is important and should be the aim whenever possible. This plate can be secured to osteopenic bone, or to bone where there is a cortical defect. The LCP Proximal Femur 4.5 uses existing screws and instrumentation. The stainless steel screws necessary for implantation are: 7.3 mm cannulated conical, 7.3 mm cannulated locking head, 5.0 mm cannulated conical, 5.0 mm cannulated locking head, 5.0 mm and 4.0 mm StarDrive locking head screws, and 4.5 mm Cortex Screws.

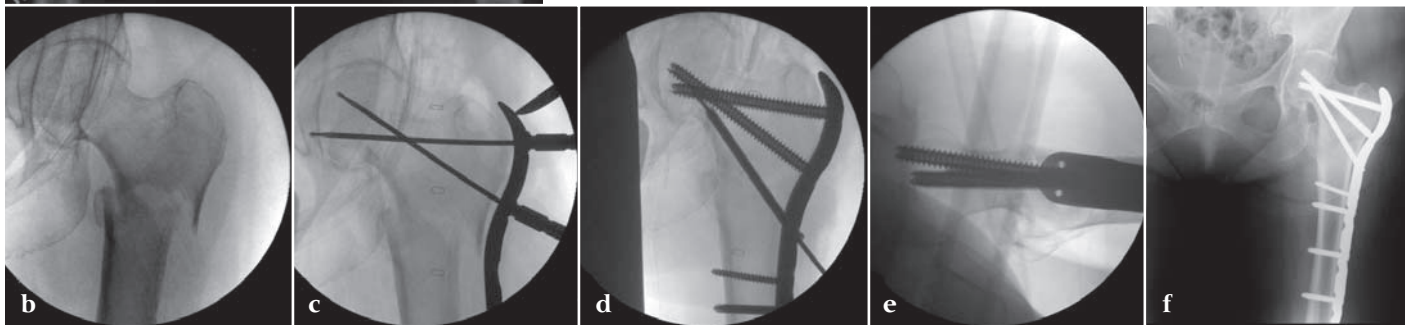
**78-year-old osteoporotic female with a left subtrochanteric femur fracture. The proximal femur has a frontal plane fracture in it. Advantages include excellent purchase of the osteoporotic proximal segment, avoidance of abductor devitalization, and reestablishment of the normal neck-shaft angle.**



**a-b Preoperative x-rays.**

**c-e Intraoperative x-rays.**

**f Postoperative x-ray.**



### 5.0 mm and 7.3 mm Cannulated Locking Head Screw

For the Condylar LCP and the Proximal Femur LCP, longer screws have been provided from 100 mm up to 145 mm. As with the existing Cannulated Screws, they feature a 4.0 mm hexagonal drive head, 2.5 mm cannulation and locking threads, and are self-drilling and self-tapping.

Jens Chapman, Robert McGuire, Mike Janssen, Paul Pavlov, Dietrich Schlenzka

## NEW SPINE PRODUCTS

### Vertical Expandable Prosthetic Titanium Rib (VEPTR)

The Vertical Expandable Prosthetic Titanium Rib (VEPTR) mechanically stabilizes and distracts the thorax without fusion in seriously ill, juvenile patients diagnosed with Thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth. Most commonly, it occurs in patients with severe rib anomalies associated with scoliosis. The overriding clinical need of this patient population is to stabilize their pulmonary condition caused by musculoskeletal deformity and to ultimately allow the continued growth of their thoracic cavity and spine.

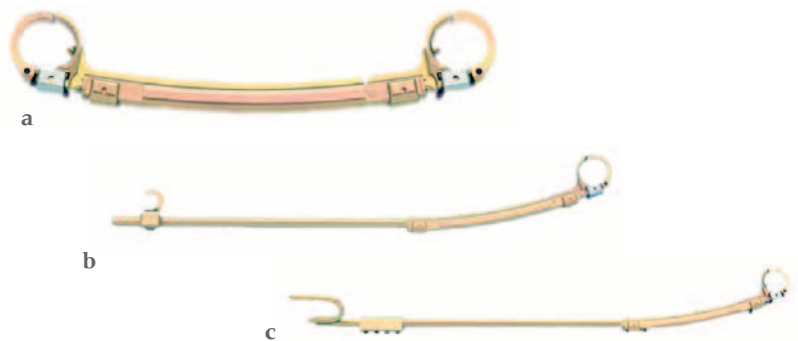
VEPTR implants are attached perpendicularly to the patient's natural ribs and lumbar vertebra or sacrum. Once VEPTR is in place, the design allows for periodic expansion of the thoracic cavity and replacement of component parts through less invasive surgery. Patients are usually very young and must be followed until skeletal maturity. As the patient grows, the VEPTR prosthesis is expanded every 4 to 6 months to accommodate the growth of the child. Eventually the prosthesis must be replaced with a longer device for expansion to continue.

Available constructs are:

The ends of the inferior and superior cradles

mate with the ribs. They are available as neutral, angled right, and angled left to best fit rib curvature. The cross-section of the rib cradles is T-shaped for enhanced strength. The rib sleeve is the central section of the construct. This acts as a track for the cradles. The distraction locks are inserted into holes at both ends of the construct to attach the superior cradle and either the inferior cradle or the lumbar extension. The position of the inferior cradle assembly along the rib sleeve depends on the desired length of the overall rib prosthesis construct. All of these configurations are required to accommodate extensive differences in anatomy that exist in these patients.

Associated manual instrumentation is available for distraction, insertion, expansion, and removal of the VEPTR.



**a Cradle-to-Cradle (Rib-to-Rib).**

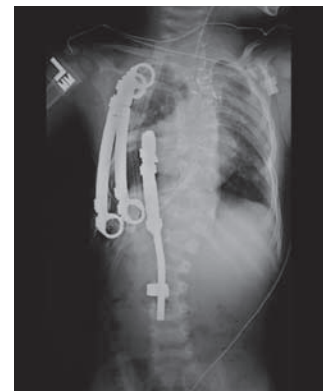
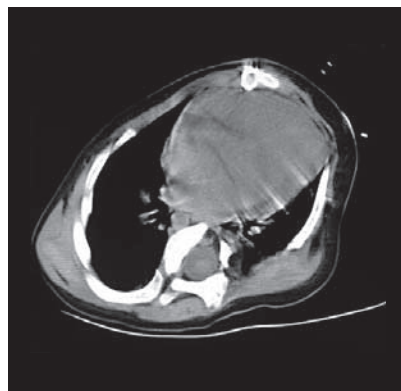
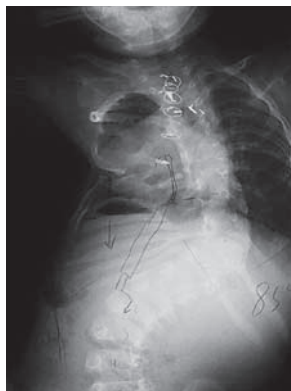
The Cradle-to-Cradle assembly is available in two different radii, 220 mm and 70 mm, and various lengths.

**b Cradle-to-Lumbar Extension (Rib-to-Lumbar Lamina).**

The Cradle-to-Lumbar Extension is available in 220 mm radius.

**c Cradle-to-S Hook (Rib-to-Ilium).**

The Cradle-to-S Hook Assembly is available in 220 mm radius.



Congenital scoliosis with fused ribs, preoperative and after treatment.





### Pre-Contoured Scoliosis Rods

The Pre-Contoured Scoliosis Rods eliminate the need for extreme rod bending in the thoracic and lumbar spine. These prebent rods match the kyphotic and lordotic curves of the spine and include a non-contoured section in the three lengths 50 mm, 65 mm, and 80 mm to match varied patient anatomies between T10 and L2. The Pre-contoured Scoliosis Rods are compatible with our pedicle screw systems. They are available in 5.0 mm and 6.0 mm diameters and offered in TAN and stainless steel.

### Axon: Persuader, 2.4 mm K-wire with stop and 3.5 mm Ti Shaft Screws

The Axon System is designed for posterior stabilization of the upper spine taking into account the variations of patient anatomy. A posterior fusion and stabilization procedure is often used to treat instabilities secondary to traumatic injury, rheumatoid arthritis, ankylosing spondylitis, neoplastic disease, infections, and previous laminectomy.

The Axon System is based on the CerviFix/StarLock System. This allows an extension of a construct from the occiput to the lower spine using the Universal Spine System (USS).

The following enhancements provide additional clinical options to surgeons using the Axon System:



#### Persuader

The Persuader makes easier the correct placement of the 3.5 Ti Rod within the head of the variable axis head of the Axon screw. The persuader will be a standard component of the Axon set.

#### 2.4 mm K-wire with stop

The 2.4 mm K-wire with stop is for surgeons who prefer a K-wire approach instead of the standard drill bit procedure.



#### 3.5 mm Ti Shaft Screws

The 3.5 mm Ti Shaft Screws have an unthreaded shaft portion (10 mm) to prevent soft tissue damage. They are available in 22–36 mm total screw length.





## Anterior Cervical Compression System (ACCS)

In the recent past, the anterior cervical plating market has been divided over the issue of semi-constrained systems—whether a semi-constrained system with its assumed benefits is better than one that is constrained. Studies seem to indicate that multilevel constructs may have lesser pseudoarthrosis and non-fusion rates when screws allow an angular rotation. A key factor to consider when creating an improved anterior cervical system is that semi-constrained systems do not compromise on the sufficiently open neural foramen which was created to achieve decompression.



In tests for load sharing of plates—with a full-length graft—constrained plates transmitted 95% of the axial load to the graft, indicating that a locked construct effectively shares load. However, when the graft was shortened by 10%, they did not share any load until 90 N were applied, and at 120 N, it shared only 17% of the load. In multilevel cervical corpectomies, clinical experience seems to indicate that anterior plating does not prevent construct failure. It is conjectured that the plate design may contribute to this. A semi-constrained construct does not significantly change strut-graft loads in extension or flexion. Thus it may be biomechanically advantageous to use these for such indications.

The Anterior Cervical Compression System for anterior cervical discectomy and fusion is indicated for anterior screw fixation to the cervical spine (C2–C7) for the following indications: degenerative disc disease (DDD), spondylolisthesis, spinal stenosis, and tumors (primary and metastatic), failed previous fusions, pseudoarthrosis, and deformity (defined as kyphosis, lordosis and scoliosis).

The Anterior Cervical Compression System (ACCS) consists of plates with cortex and cancellous bone screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine (levels C2–C7). The system uses preformed plates that are designed to follow the anatomy of the cervical spine.

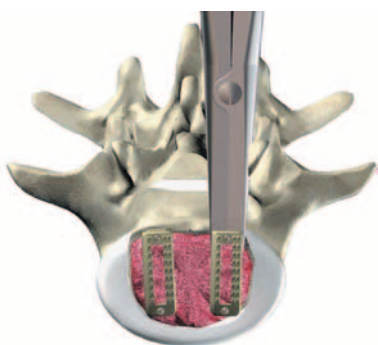
Additional features of the Anterior Cervical Compression System:

1. Allow the creation of a rigid construct.
2. Allow angular settling of the screw with respect to the plate as an alternative to the fully rigid construct.
3. Anatomical alignment—therefore preformed.
4. Low profile and footprint—2.0 mm thick and 16 mm wide.
5. Quick reconstruction—therefore one-step locking screw-plate interface.
6. Variable angulation—up to 12° cephalad and caudal angles to enable ease of screw insertion with anatomical alignment.
7. Fixed angle screws (at 4° only—cephalad and caudal) to build a rigid or a hybrid construct.
8. Graft visualization through dogbone feature.
9. The screw will enable self-retention and a higher yield torque.
10. Wider range of screws (cortex and cancellous) with additionally available screw lengths and respective drill lengths.
11. Simple and few instruments.
12. Simpler and more intuitive graphic case for the OR personnel.

### 4.5 mm Ti Cancellous Expansion Head Screws, self-tapping and 3.0 mm drill with Quick Connect

Expansion Head Screws are used for multilevel corpectomies with the CSLP system. Additional to the existing 4.0 mm cortex screws in 18–20 mm lengths and 4.5 mm cancellous screw to a maximum length of 16 mm, there are now available 4.5 mm Ti Cancellous Expansion Head Screws in 18–20 mm to provide better bone purchase in these multi-level corpectomies.

The screws are used with the corresponding 3.0 mm drill bits with stops, 18–20 mm.



### PLIVIOS Revolution: implants and instruments

For the surgical treatment of degenerated lumbar discs, cages can be used in order to restore disc height and the lordotic curve. A mechanically stable and durable device such as PLIVIOS or Contact Fusion Cage can be used.

The new PLIVIOS implants are based on the clinically established PLIVIOS and Vertebral Spacer-PR concept. The open structure and the interface to the implant holder is the same. In order to ease the rotation of the implant, one row of teeth has been removed and is replaced by a chamfer. The cross-section is adapted to the Contact Fusion Cage sizes of 7 × 8 mm, 9 × 8 mm, 10 × 8 mm, 11 × 9 mm, 12 × 10 mm, 13 × 10 mm, and 15 × 11 mm.

The implants provide two lordotic angles of 4° and 8°.

All implants are available empty or prefilled with chronOS block material.

PLIVIOS provides benefits in dorsal arthrodesis with cage by preserving the integrity of the endplates and their stability.

### New instruments

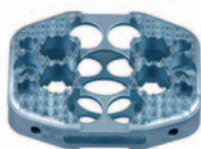
The Nerve Root Retractor is a new protection instrument which allows a safer access to the intervertebral space through the posterior access. The frontal blades are inserted between the nerve root and the dura. The metal blades protect the mentioned neural structure from major damages, eventually caused from the toothed implant.

The Packing Block comprises four cavities for the individual width of the implants.

Two new Trial Implants as a line extension to the existing PLIVIOS Trial Implants in 10 mm and 12 mm.

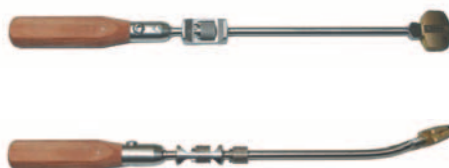
The Implant Holder has a strengthened shaft with a keel which avoids the shearing-off of the instrument. The shaft elements are rounded in order to avoid mechanical stress to the surrounding tissue while rotating the instrument. The transition of the tips to the shaft is rounded in order to reduce the risk of breaking.





### SynCage–Extra Extra Small (XXS)

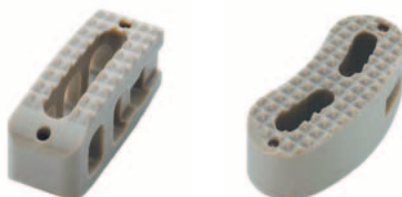
For higher level SynCage treatment in the lumbar spine, a 12 mm SynCage in stainless steel has been developed. A specific Trial Implant and an Implant Holder is available to fit this new size.



### Detachable Trial Implant Holder for SynCage and SynCage-LR

While performing one or multi-level ALIF surgeries—using Syn-Frame—it is advantageous to reduce the amount of “hardware” in the operation field. Particularly in situations when the position of the Trial Implant is to be evaluated with an image intensifier, a temporary instrument (handle) removal is recommended.

With the Detachable Trial Implant Holder for SynCage, which is available in a straight and in a bent version, both in stainless steel, this can be achieved. These instruments follow a modular concept where the parts of the existing instruments can be exchanged. Easy disassembling enables quick postoperative cleaning.



### Wide Vertebral Spacers and instruments

For optimal fusion, large amounts of bone graft as well as structural support are necessary.

The increased axial canal in the current Vertebral Spacer allows for additional bone graft, or bone graft substitute to be packed inside, thus enhancing the fusion. The strength of the spacers was maintained by increasing the outer dimensions.

Since the vertebral body size and shape vary by patient, longer and wider implants are available to select the implant that best matches the specific patient’s anatomy.



The Vertebral Spacer-TR now additionally features 10 mm wide by 30 mm or 33 mm long, 12 mm wide by 27 mm, 30 mm long, or 33 mm long.

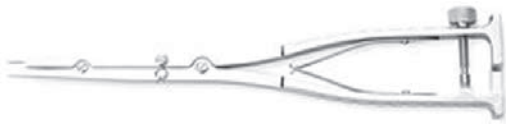


The Vertebral Spacer-PR line extension features 8 mm wide by 24 mm long, 10 mm wide by 22 mm or 24 mm long, and 12 mm wide by 22 mm, or 24mm long.



### T-PLIF & PLIF Trial Spacers

Trial Spacers in both the regular style as well as the detachable style are offered for every footprint in each available height.



#### T-PLIF & PLIF Implant Holder

The new PLIF Implant Holder is adapted to the increased width of the implants. It is compatible with all new Vertebral Spacer-PR implants, as well as the existing allograft implants, Vertebral Spacer-PR, and Syn-Cage Narrow implants.

#### Click'X: additional instruments

The Click'X low back system is indicated for posterior stabilization of instabilities and degenerative diseases in the posterior lumbar and sacral spine.

Additional instruments have been developed to improve overall handling.



#### Click'X Holding Forceps straight for rods

It replaces existing Holding Forceps to provide a smaller width of the frontal grip element, allowing for easier manipulation.



#### Click'X Holding Forceps curved for rods

The additional curvature of the front element of the Holding Forceps allows for easier simultaneous manipulation during tightening of locking screw.



#### Click'X Protection Sleeve

The Sleeve protects the soft tissue from the pedicle screw thread when the sleeve is pushed over the screw.



#### Click'X Distraction Forceps

The Distraction Forceps allows for direct distraction on pedicle screws prior to Click'X head assembly, ie, allowing for easy posterior cage placement.

### Ti Click'X Monoaxial Pedicle Screw System

Conditions involving fractures and tumors often require the stabilization of pedicle screws through posterior fusion.

The Click'X Monoaxial Screw and Hook System is indicated for stabilization of spinal segments, as an adjunct to fusion, in the treatment of deformity and degenerative diseases. Deformity indications include scoliosis, kyphosis, lordosis, and Scheuermann's disease. Degenerative indications include degenerative disc disease, spondylolisthesis, and stenosis. Monoaxial screws, hooks, rods, and locking caps offer stable fixation to the spine during the bone fusion process. Specialized instruments allow surgeons to safely and effectively insert screws, place hooks, contour and reduce rods, all of which will reduce pain and blood loss while stabilizing and correcting the spine during fusion.



#### Ti Click'X Monoaxial Pedicle Screws

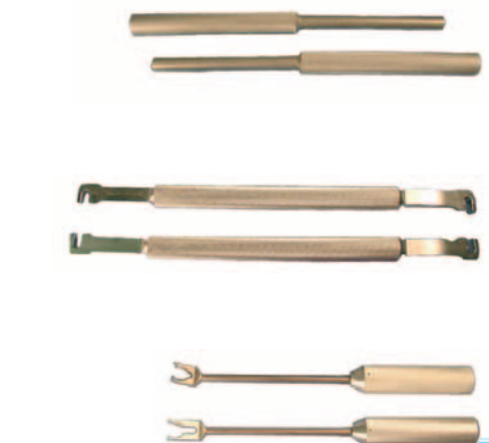
Ti Click'X Monoaxial Screws are available in 4.2 to 9.0 mm diameters and 25 to 100 mm lengths. The 90 and 100 mm screws address the clinical need for sacral-iliac fixation. Click'X Monoaxial Screws feature a dual-core thread design for faster insertion.

#### Ti Click'X Hooks

The Click'X Hooks offering includes pedicle, transverse process, and lamina hooks. The Click'X Lamina Hooks are available in a variety of sizes and angulations including up- and down-angled, tall-body, offset, and thoracic lamina hook geometries.

#### Ti Click'X Monoaxial Pedicle Screw System instruments

New instruments for the Click'X Monoaxial Set include ergonomic, silicone-handled hook preparation instruments, hook placement forceps, self-retaining footed screwdrivers, rod benders, and rod reduction instruments including rocker forks and a bi-planar persuader.





### Less Invasive Click'X instruments

Lumbar degenerative diseases can be treated with pedicle screw and rod fixation devices that provide immobilization and stabilization of the spine during fusion. Minimally invasive techniques are used to reduce tissue trauma and improve patient morbidity and pain, while reducing the length of hospital stay.

The less invasive Click'X System provides a mini-open, minimally invasive technique that allows posterior decompression, interbody fusion, and pedicle screw insertion through a smaller lateral incision.

### Approach instruments

The Obturator allows placement over a K-wire to dilate the posterior spinal muscles and allow insertion of the 3-Blade Retractor.

The Dilators and Obturator allow incremental dilation of the posterior spinal muscle over K-wire and allow insertion of the 3-Blade Retractor.

The 3-Blade Retractors feature a medial and a lateral version for retraction of the medial and lateral spinal muscles. Different working lengths accommodate the patient anatomy. The ability to nest the medial and lateral retractors provides simultaneous medial and lateral spinal muscle retraction. The low-glare finish reduces reflection.

### Click'X instruments

The Slotted Rod Guide attaches to the standard and preassembled Click'X 3-D heads to facilitate rod placement.

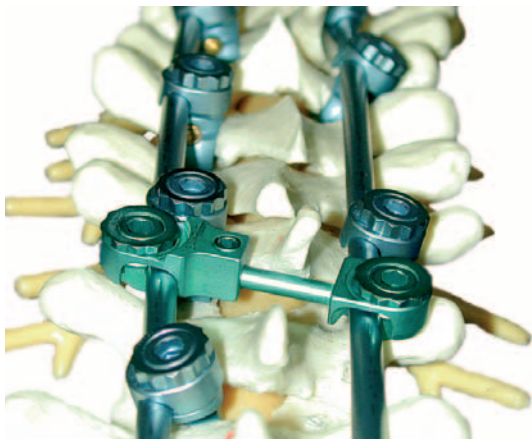
The 3-D Head Pusher allows attachment of the Click'X 3-D to a standard Click'X screw when used in conjunction with the Slotted Rod Guide.

The Click'X Implant Positioner's geometry aligns the 3-D head saddle to allow rod placement in adjacent screws.

The Rod Holding Forceps small size allow visualized rod placement into the Click'X 3-D head.

The Knurled Handled Screwdriver allows application of the locking cap through the Rod Pusher or the Slotted Rod Guide.





### USS II: cross-links

Cross-link connectors are transverse stabilizers linking the two longitudinal rods. They are recommended for unstable fractures and multi-segmental constructs in thoracic and lumbar spine and posterior spinal deformity correction and stabilization. The 3.5 mm rods can be bent according to anatomy. Together with the cross-links, they absorb the transversal forces and prevent parallel displacement of the spinal rods, which increases the stiffness of the construct.

The new cross-links minimize tissue irritation due to a profile 2 mm lower than existing cross-links. The cross-link connectors can be assembled in various combinations. An easy click-on mechanism allows to preassemble a cross-link construct which is then placed on the two longitudinal rods.



### USS II: Holding Sleeve and Nut

The Holding Sleeves and Nuts are new parts of the USS II which is indicated for the correction and stabilization of the spine.

Placement of the Nut and Holding Sleeve for 5 mm or 6 mm rods on hooks or screws is now possible in one single step.

The holding sleeve is to be used in combination with the existing straight-handled socket wrench

Lim Cheung, Ralf Gutwald, Richard Haug, Bradley Strong

## NEW CRANIOMAXILLOFACIAL PRODUCTS



### Rapid Resorbable Fixation System

The Rapid Resorbable Fixation System is primarily intended for treatment of pediatric patients suffering from craniosynostosis which causes premature skull fusion, resulting in impeded skull growth, and increased intracranial pressure. The Rapid Resorbable Fixation System can also be used in non-load bearing applications such as maintaining the relative position of and/or containing bony fragments, bone grafts or bone graft substitutes in reconstruction or mandibular areas.

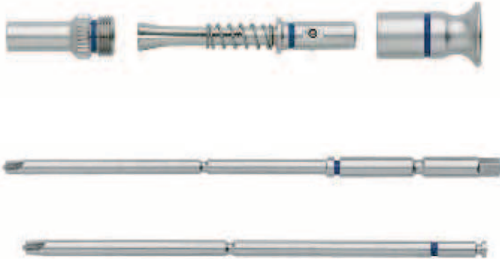
The Rapid Resorbable Fixation System consists of a complete line of plates, meshes, sheets, and screws in a faster-resorbing polymer [85:15 poly (L-lactide-co-glycolide)]. The polymer resorbs within approximately twelve months by bulk degradation and hydrolysis without the late inflammatory complications and foreign body responses observed with semi-crystalline structures. The polymer strengths are not affected by radiation therapy.

A variety of shapes and sizes is available. Additional shaping to the contours of the anatomy is possible by heating or cutting to the desired shape. The instrumentation, eg, in situ Bender/Cutter of the existing Resorbable Fixation System can be used.

The Resorbable Screws come in thread diameters of 1.5, 2.0 and 2.5 mm and lengths of 3.0 to 8.0 mm.

The Resorbable Plates offer screw diameters of either 1.5 or 2.0 mm. The plate thickness varies from 0.5, 0.8 to 1.2 mm. They come in the following shapes: straight, adaption, orbital rim, orbital floor, oblique-L, Y, X, strut, and burr-hole cover.

The Resorbable Meshes are available in 0.25, 0.5, 0.8, and 1.2 mm thickness, and either square, round, or crescent shape.



### Resorbable Fixation System: Screwdriver with Holding Sleeve

Screwdrivers for Resorbable Screws have been developed which provide a superior pick-up of screws compared to the old screwdrivers. The new screwdriver shaft with holding sleeve was designed as the successful screwdrivers from the 1.3 Compact Craniofacial Set. The 1.5 mm and 2.0 mm Screwdrivers with Holding Sleeves are available with mini-quick or hex coupling in a short, or long, version.

### Resorbable Fixation System: Bending Templates

Bending Templates for the different plates of the Resorbable Fixation System are now also available in stainless steel. These Bending Templates are much more stable than the existing ones in titanium. They can be bent several times without breaking. The Bending Templates are available for the 1.5 and 2.0 mm Adaption Plate with 8 and 20 holes, 1.5 mm Strut Plate with 20 and 36 holes, 2.0mm Strut Plate with 20 holes, 1.5 and 2.0 mm L- Plate with 10 holes, 1.5 and 2.0 mm Y-Plate with 10 holes, 1.5 mm Double-Y-Plate with 10 holes, 1.5 and 2.0 mm Orbital Plate with 10 holes, and the 1.5/2.0 mm Mesh Plates.



### Resorbable Tack System: Drill Bits

The implantation of Resorbable Tacks requires the Tack hole to be drilled with a Drill Bit from the Resorbable Fixation System. These Drill Bits are specific to each Tack diameter and length. The eight new Drill Bits correspond with the existing Resorbable Tacks (3, 4, 5, and 6 mm long) from the 1.5 mm Resorbable Fixation System. The Drill Bits are available either with Stryker J-Latch coupling or with hex coupling. Additionally a 1.65 mm Drill Bit, Stryker, J-Latch with 6 mm stop, 44.5 mm long enables to augment the 2.0 mm Resorbable Screw, Drill and Tap System.



### Low Profile Neuro Plates

The Low Profile Neuro System is designed to close bone flaps quickly, enable stable internal fixation, and address particular neurosurgical problems with a very low plate/screw profile. Three new plates widen the existing system.



### Temporal Mesh

The Temporal Mesh is designed for a neurosurgical access procedure where a "keyhole" shaped perforation is made in the temporal region of the skull. This perforation is performed with a rotary burr which leaves no bone flap to be repositioned after surgery. The preshaped mesh covers the bony defect and prevents temporal hollowing. The Temporal Mesh is offered in two sizes; 1.3 mm and 1.6 mm.



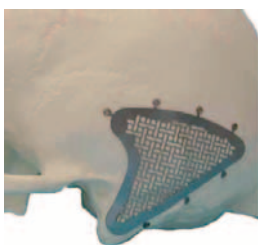
### Adjustable Strut Plate

The Adjustable Strut Plate is an 8-hole plate providing multiple points of fixation for a craniotomy bone flap. These bone flaps are variable in size and shape, and the plates offer the ability to be readily contoured in-plane to adapt to a wide variety of curvatures. They are offered in two sizes; 1.3 mm and 1.6 mm.



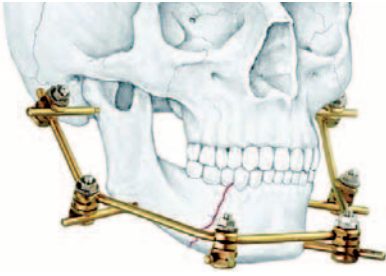
### 5-Lobe Burr Hole Cover

The Five-Lobe Burr Hole Covers are adaptations of the current (6-lobe) burr hole covers. In cases where a catheter, shunt, or drain must protrude through the skull, these plates provide an opening for passage while still securing the bone flap in place. They are offered in three sizes; 1.3 mm, 1.5 mm, and 1.6 mm.



### Low Profile Neuro Contourable Mesh, Malleable Mastoid, medium

The Low Profile Neuro System has been enhanced by a medium sized mesh for the mastoid. This mesh is a triangular shaped piece of contourable mesh with ears allowing fixation in the mastoid region of the skull. Due to the contours found in the mastoid area, this malleable, triangular shape is advantageous for procedures where the bone is osteotomized. It can also be used as a crib to assist in reconstruction of the mastoid area using bone substitutes.



### Mandible External Fixation Set

The Mandible External Fixation System stabilizes and provides treatment for fractures of the mandibular area, including severe open fractures, highly comminuted closed fractures, nonunions, and delayed unions (especially associated with infection), fractures associated with infections, tumor resections, facial deformity corrections, gunshot wounds, panfacial fractures, burn maintenance, and bone grafting defects.

### Internal Midface Distractor System



The Internal Midface Distractor provides an internal distraction device to correct severe midface retrusion and to treat patients born with craniofacial anomalies that result in severe midface deficiencies, including Apert Syndrome, Crouzon Syndrome, and Pfeiffer Syndrome. These syndromes produce severe midface retrusion and severe intracranial pressure which can lead to upper airway obstruction, degenerative vision, ulcerations of the cornea, potential blindness, sleep apnea, and psychosocial disorders.

The Internal Midface Distractor System provides several advantages in treating midface deficiencies over conventional osteotomies and bone grafting. For example, a LeFort III osteotomy in combination with bone grafts and rigid internal fixation is limited to approximately 10 mm of advancement due to the magnitude of the resulting soft-tissue forces resisting the advancement. Patients with severe midface retrusion of up to 40 mm can be treated with the Internal Midface Distractor System in a single procedure because substantial soft-tissue forces exerted on the midface can be overcome.

The Internal Midface Distractor System also provides the ability to minimize relapse associated with the advancement. Employing distraction to correct these deformities provides

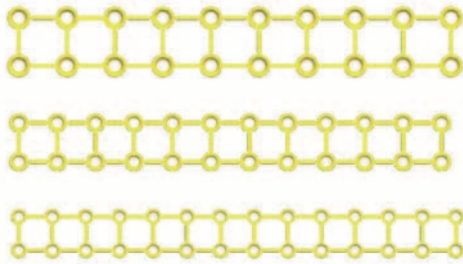
a slow, controlled means for overcoming the forces of soft-tissue resistance which leads to an expectation (supported by clinical studies) of a lesser degree of relapse. The presence of a buried distractor during bone consolidation further provides a rigid construct to counteract the soft-tissue forces until the bone has fully consolidated.

The Internal Midface Distractor System consists of a telescoping barrel attached to an anterior and a posterior footplate. It is placed subcutaneously with the anterior footplate fastened to the lateral orbital rim, extending down to the maxilla and spanning the zygomaticomaxillary suture, and the posterior footplate fastened to the temporal region of the cranium. The barrel of the distractor body lies sagittally against the cranium underneath the temporalis muscle, and its posterior end extends percutaneously into the external environment for activation. In a typical case, two devices are attached (one on each side) for advancement of the midface.

The outer barrel of the distractor body is threaded to accept both a hex nut and the posterior footplate. The posterior footplate is a fifteen-hole plate that can be moved anywhere along the threaded portion of the distractor body in 0.5 mm increments. The hex nut fixes the position of the posterior footplate once it has been chosen. The anterior footplate attaches to the distractor body by a tongue and groove connection. This allows the surgeon to select from amongst five different styles of anterior footplates to fit the patient's anatomy. A small machine screw can be used to rigidly secure the anterior footplate to the distractor body, or, if the machine screw is not used, the distractor body can be easily separated from the anterior footplate during removal without performing a full coronal incision. This enables a quick removal procedure of the distractor while leaving the anterior footplate implanted.

The device is offered in one length for up to 40 mm of distraction. The activation end of the device extends into the external environment on smaller patients, or, in the case of larger patients, an optional extension can be attached by a machine screw to lengthen the device. The extensions are offered in three versions: a rigid extension (20 mm length), an extension incorporating a universal joint (20 mm length), and an extension incorporating a flexible cable (40 mm length). The activation end of the distractor and the extensions engage with the patient screwdriver for advancements in 0.5 mm increments.





### Craniofacial Plates

The existing Craniofacial Set has been extended to include longer length Strut Plates, the 2.0 mm Strut Plate with 20 holes, 1.5 mm Strut Plate with 24 holes, and 1.3 mm Strut Plate with 26 holes. These new Craniofacial Plates can span across a longer distance to stabilize larger, comminuted fractures.



### Adaption Plates

Shorter Adaption Plates (6 and 8 holes without intersection bars) for the 1.3 mm and 1.5 mm Compact Craniofacial Set will minimize unnecessary cutting. For the 1.5 mm Compact Craniofacial Set shorter Adaption Plates with intersection bars are provided with 4 and 6 holes. The Adaption Plates can be bent in plane with the 3-Prong Bending Pliers of the 2.0 mm Compact Craniofacial Set.

### 1.0, 1.3, 1.5, and 2.0 mm Craniofacial Screws with PlusDrive Recess

Craniofacial Screws and Emergency Screws are now available with PlusDrive Recess in 1.0 mm, 1.3 mm, 1.5 mm, and 2.0 mm dimensions. The first clinical issue being addressed is the need for cruciform self-drilling screws for both self-tapping and self-drilling screws. The screws also feature an improved retention at the cruciform screw/blade interface. For all screws a self-retaining Screwdriver Blade is offered. The 1.0 mm PlusDrive Self-Drilling Screws are currently under development and will follow at a later stage.

### 2.0 mm Cruciform Screws with PlusDrive Recess

The 2.0 mm Ti Locking Screw, self-tapping and self-drilling, the 2.0 mm Ti Cortex Screw, self-tapping and self-drilling, and the 2.0 mm Emergency Screw are now available with PlusDrive Recess. PlusDrive makes screw reengagement easier and improves blade screw retention significantly. More effective application of screws intraorally at an angle and for retaining longer length screws are additional advantages. A corresponding 1.5 and 2.0 mm Plus Drive Screwdriver and the respective self-retaining Blades are available.



### **2.0 mm Mandible Locking Plate Set: Double Angle Plates**

The 2.0 mm Mandible Locking Plate is the standard plating system for mandible trauma and reconstruction. This system is now extended to include Double Angle Plates. They are provided in two thicknesses, large (1.5 mm) and extra (2.0 mm). Specific Bending Templates for the Double Angle Plates are available.

The plates are designed for reconstruction and trauma cases which need a both sided fixation. Bending and adaption will be easier due to the anatomical preforming.



### **2.0 mm Mandible Locking Plate Set: Swivel-Fixed Screwdriver**

The Swivel-Fixed Screwdriver is designed for the manual insertion and placement of 2.0 mm, 2.4 mm and 3.0 mm maxillofacial screws used in maxillofacial surgery. The ergonomic screwdriver handle has a single assembly design which makes it easy to use, and is available in one size. It provides for two operating positions—swivel (rotating) and fixed (locked). The screwdriver accepts all maxillofacial hex coupling blades/taps.

### **2.0 mm Mandible Locking Plate Set: Mandible Screw Caddy**

For the 2.0 mm Mandible Locking Plate Screws a new Screw Caddy is available which is more cost effective. It fits into the graphic case of the 2.0 mm Mandible Locking Plate Set.

Sabine Goldhahn

## NEWS FROM AO CLINICAL INVESTIGATION & DOCUMENTATION (AOCID)

### chronOS™ Inject study

In a previous issue (TK News 01/2004) bone substitution materials were presented, showing the course development from ceramics to chronOS™ Inject, a new CE marked, injectable, mouldable, and biocompatible calcium phosphate bone substitute with resorbing and bone remodeling properties. It is the first available artificial bone substitute based on brushite, a resorbable calcium phosphate phase also found in the body in addition with  $\beta$ -tricalcium phosphate granules. Through resorption of the brushite phase an open-porous structure is created which allows the blood vessels and new bone to grow into the pores. chronOS™ Inject is intended for use as a bone void filler for the repair of bone defects caused by traumatic injury or surgical intervention and for reconstruction of bone defects. As an injectable bone substitute, it can also be injected into complex geometrical bone voids, such as removed bone cysts or remaining

defects in comminuted fractures, and complicated manual preshaping of bone substitute forms can be omitted.

It consists of a powder mixture on a calcium phosphate basis and a liquid component. After mixing these two components, chronOS™ Inject transforms into a composite material consisting of  $\beta$ -tricalcium phosphate granules with a defined, pore structure and a brushite matrix. The  $\beta$ -TCP granules are resorbed slower than the brushite matrix and serve as an anchor for the newly formed trabecular bone (Fig 1a–b).

chronOS™ Inject is ready to use two minutes after the two components have been mixed, and the application should be carried out within the following three minutes (Fig 2). Six minutes after injection and modeling the primary treatment is completed.

Several limitations for similar injectable or calcium phosphate bone substitutes are known. chronOS™ Inject has a mechanical strength comparable with spongiosa and therefore needs a stable internal fixation of fractures prior to injection.

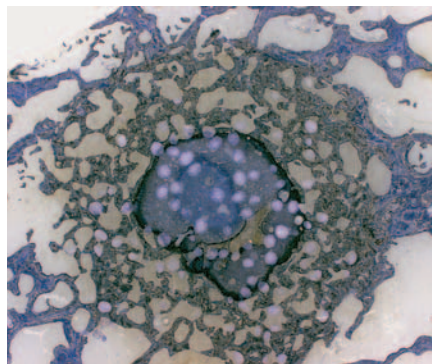
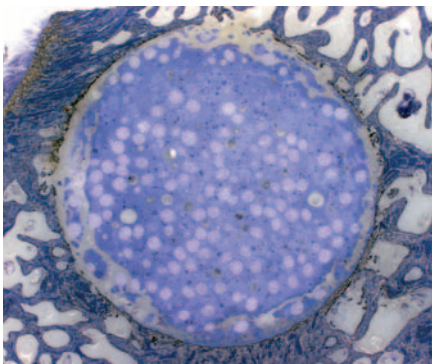


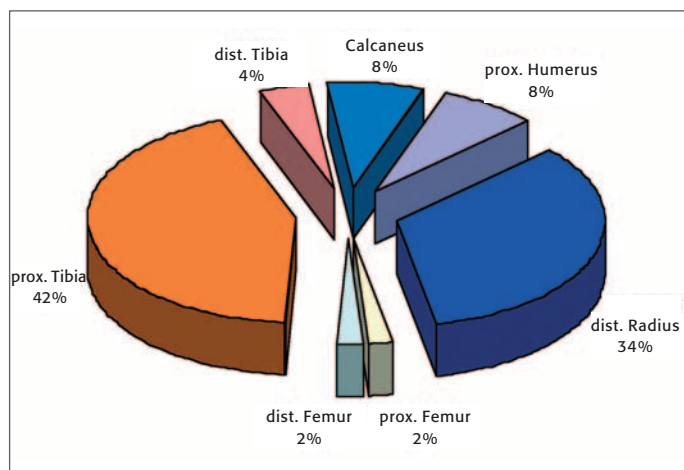
Fig 1a–b

- a Histology of a bone defect filled with chronOS Inject 2 weeks post-operative (drill hole  $\varnothing$  8 mm, distal femur of an adult sheep). The  $\beta$ -TCP granules are visible as pale blue areas within the (darker) matrix.
- b Histology of a bone defect filled with chronOS Inject 24 weeks postoperative. New bone formation occurs from the periphery toward the center.

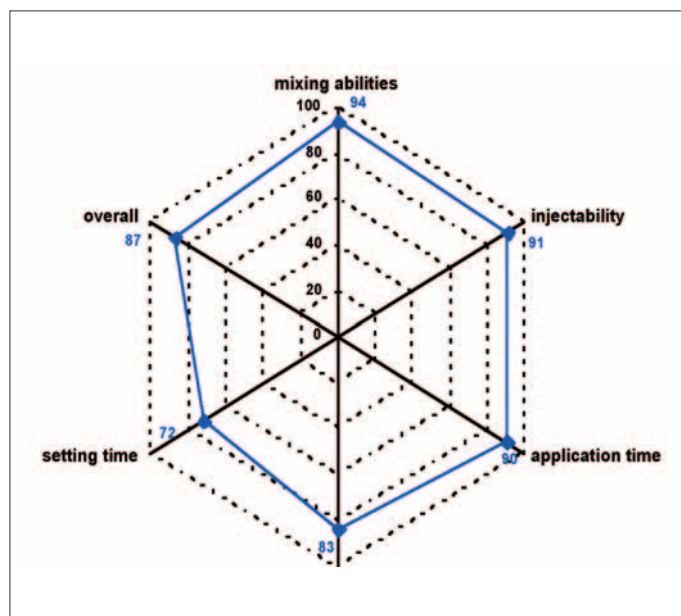


Fig 2

Application gun for the injection of chronOS Inject.



**Fig 3**  
Distribution of cases according to fracture type (n=53).



**Fig 4**  
Product characteristics of chronOS inject measured with the visual analogue scale. The value 100 means “very satisfying” (n=53).

A prospective multi-center study has been conducted since January 2004 by the AOCID to investigate the safety of chronOS<sup>TM</sup> Inject as bone void filler and to evaluate possible complications. A particular interest had been paid to specific complications associated with bone substitutes, for example cement leakage into the joint and fragmentation. Secondary objectives are the assessment of the operative handling by the performing surgeons and the functional outcome of the patients. At the moment 53 patients from 6 sites have been included showing several indications (Fig 3).

52 % of the study-patients are male, 58 % are female. The mean age is 52, with a range from 26 to 85.

In order to fulfil the eligibility criteria a stable internal fixation has to be performed. The treatment has to be applied within the first 6 weeks after the injury had occurred. Follow-up of the patients is performed 6 months after the primary treatment with focus on postoperative complications and the general satisfaction of the surgeon as well as the patient.

A preliminary analysis of the baseline data and the first 12 follow-up's showed that there occurred no other major complications than described in the literature. One of the 53 patients suffered from a wound infection, another patient had a complicated wound healing and a loss of reduction. The overall satisfaction rate of the surgeons was 92 (visual analogue scale) at the 6 month's follow-up. Regarding the handling characteristic, the majority of surgeons was very satisfied with chronOS<sup>TM</sup> Inject. The values of the rating of the single product characteristics (visual analogue scale) is shown in figure 4.

Romano Matthys

## NEWS FROM THE AO DEVELOPMENT INSTITUTE (ADI)

The ADI Development Service offers innovative solutions to common problems and support for research projects and educational activities.

### LiLouPen (Light Loup Pen)

The change of screw mechanism from a hexagon socket to StarDrive™ combined with minimally invasive techniques of implant removal place new demands on the surgeons and their instruments.

In order to remove the screws it is important to identify the size and the type of screw mechanism without having to expose the implant by surgical dissection.

The size of the screw can generally be identified radiologically with reference to the anatomical region, but the screw mechanism generally cannot.

The LilouPen has been designed to meet this need. It is the realization of a straightforward endoscopic procedure for the purpose of identifying the screw mechanism, freeing the screw head from ingrowing soft tissues, and positioning the screwdriver.

The pen is made from a transparent material, either glass or synthetics. Glass has the advantage that an optical reference (hologram) can be recorded. A synthetic material permits simple surface treatment in the sense of a Fresnel lens for light input. In a bright operative environment the image needs to be illuminated and displayed with as little dissipation as possible. The light for the illumination comes from sources in the environment (theater lights) or from a small LED attached to the pen.

A cylindrical retractor is used to expose the field of view, whereby the soft tissues between the end of the pen and the implant can be pushed away radially. The retractor consists of an expandable, cylindrical sleeve. The LilouPen is especially useful when the implants are covered by a thick, soft-tissue layer.

### GenFrac

Exploration of molecular biological approaches influencing fracture healing are restricted to the mouse model for experimentation. The reason for this is that it is virtually only the mouse that can be used as a knock-out animal.

GenFrac is the only device available worldwide with the following combined features:

1. Application for compression osteosynthesis or internal fixation.



**Fig 1**  
View of the LiLouPen, designed to feed light from the environment into the optical waveguide.



**Fig 2**  
Visual field obtained clearly showing the implant and type of screw mechanism.

2. Defined, adjustable flexibility of the fixation element.
3. Low own weight, consequently, few artifacts.
4. Good standardized procedure.

The objective was to develop an internal fixator for the mouse femur.



Currently, the internal fixator, the necessary instrumentation and OP technique have been realized technically and in vivo evaluation is underway. The small size (screw diameter 0.35 mm) requires watch-making techniques.

This internal fixator makes it possible for the user to stabilize the mouse femur with a conventional bridging osteosynthesis or by interfragmentary compression as preferred. The stiffness of the osteosynthesis can be adjusted freely as required for both techniques. The osteotomy is performed with a Gigly saw (outer diameter=0.2 mm) after the plate has been applied.

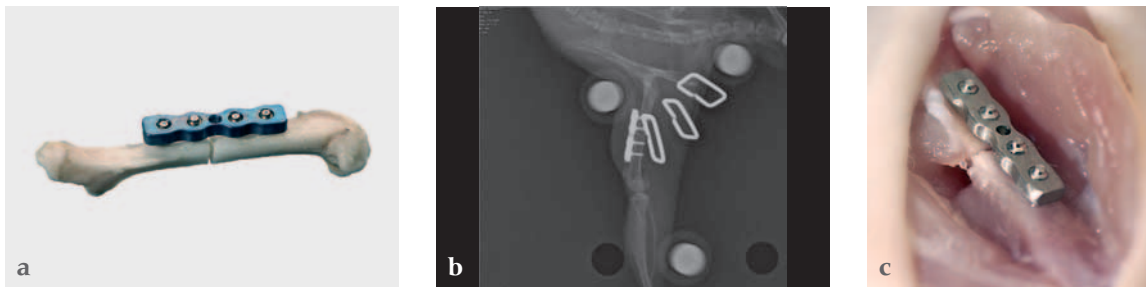


Fig 3a-c

a View of an osteotomized mouse femur with the internal fixator "MouseFix".

b Postoperative x-ray of an osteotomized mouse femur treated with the "Mouse-Fix".

c Intraoperative view.

### Technical parcoure

A technical parcoure emerged at the most recent AO Courses in Davos in close collaboration with Dr E Gautier with the above as its motto and was implemented for the first time during the "Swiss Residents Course".

The main objective of the technical parcoures is to improve the surgeon's manual dexterity and understanding of technical aspects. The following demonstrations, measurement and exercises serve this purpose:

**Mechanics of plate fixation:** stiffness of plate fixations—loading of the plate—loading of the plate screws.

**Mechanics of intramedullary fixation:** nail design—conventional nailing—locked nailing.

**Techniques of reduction:** direct and Indirect reduction—reduction.

**Clamps Difficult Implant removal:** problems and solutions.

**Assessment of surgical skills:** torque measurement of bone screws—heat generation during drilling—soft-tissue penetration during drilling—fracture healing—strain of interfragmentary tissue.

**Mechanical quiz:** estimating stiffness of different designs.

A revised and simplified version of the above with appropriate hands-on models and posters as portable educational modules will be devised in collaboration with course personnel and staff members from Synthes.

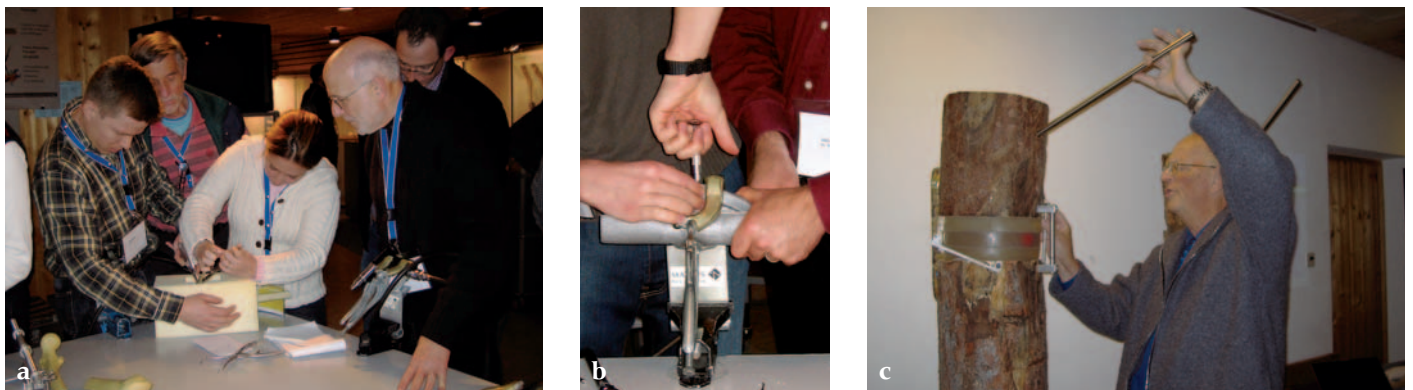


Fig 4a-c Technical parcoure, Swiss Residents Course, AO Course Davos, 2004.

Berend Linke, Jan Korner, Erich Schneider

## NEWS FROM THE AO RESEARCH INSTITUTE (ARI)

### Angular stability is beneficial for distal humeral fracture fixation in osteoporotic bone.

#### Objective

Fracture fixation in osteoporotic bone is still a considerable problem in trauma surgery, especially in the metaphyseal areas. Postoperative loss of reduction is observed frequently. Current implant developments for fracture fixation at the distal humerus incorporate the locked screw concept (LCP) as well as the concept of anatomically preshaped plates which allow placement of several screws of smaller diameter within the metaphyseal regions (Distal Humerus Plate–DHP).

The purpose of this study was to biomechanically investigate whether these implant concepts are advantageous in the treatment of distal humeral fractures if compared to Conventional Reconstruction Plates (CRP).

#### Materials/methods

Three groups (CRP n=8, LCP and DHP n=12) of human cadaver humeri were formed with similar distributions of bone mineral density (BMD, obtained by pQCT). In each specimen an unstable “low” distal humeral fracture (13-C2) was simulated by means of an intraarticular, sagittal saw cut of 0.5 mm thickness and a 5 mm supracondylar osteotomy gap representing metaphyseal comminution. In all groups double plate osteosynthesis was performed in 90° configuration according to standard AO technique.

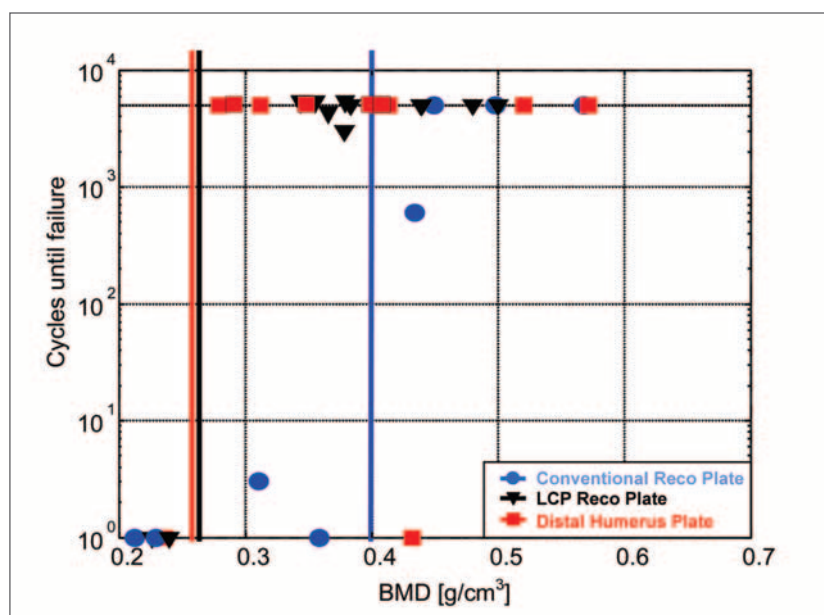
Cyclic loads of 150N were applied in flexion up to 5000 cycles. Physiological conditions of force transmission were used (60% applied to the capitulum, 40% to the trochlea). Relative fragment movements were determined in the frontal and sagittal planes. Criteria for failure were screw pull-out or distal fragment rotation of more than 5° in the sagittal plane.

#### Results

No differences between the 3 groups were apparent at BMD values above 0.4 g/cm<sup>3</sup>; all specimens survived the full test duration. DHP



Implants tested: conventional reconstruction plates, LCP reconstruction plates and distal humerus plates (from left) applied to human distal humerus specimens in 90° configuration.



Number of cycles to construct failure in a cyclic loading experiment vs bone mineral density. Lines indicate failure-limits for the 3 groups.

and LCP implants (2/12 failures each) showed improved resistance to implant or screw loosening as compared to CRPs (5/8 failures) with decreasing BMD.

The improvement was quantified by the borderline of BMD, below which the constructs were likely to fail (failure-limit). This failure-

limit was located at higher BMD values for the CRP group (0.4 g/cm<sup>3</sup>) than for the LCP and DHP groups (0.25 g/cm<sup>3</sup>).

### Conclusion

Anatomically pre-shaped plates with several metaphyseal screws and locked screw concepts improve stable fracture fixation of the distal humerus, especially in osteoporotic bone.

Norbert P Haas

## AOTK PRIZE 2004



### AO Innovation Award

Stephan Perren, MD, has been awarded the AO Innovation Award for his lifetime achievements and exceptional contributions to the development of new concepts, technologies, and treatment options.



### AO Recognition Prize

Norbert Haas (left) awarded Drs Emanuel Gautier, Switzerland (middle) and Michael Schütz, Australia (right) with the AO Recognition Prize for their outstanding contribution to the development and implementation of new concepts, implants, and instruments.



Andy Weymann

## AO EDUCATION GOES ONLINE

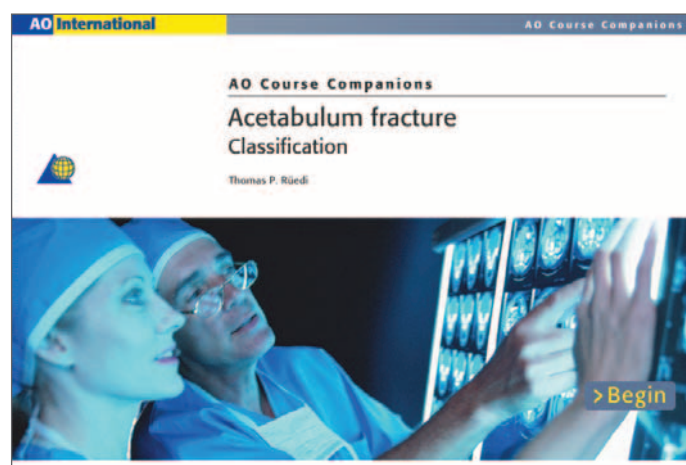
AO has spent the past year preparing for a major shift in the way it provides education. The current model, based on a combination of classroom training and textbook publications, was identified as having a number of key limitations. In the past, we were not giving surgeons enough opportunity to apply their knowledge to real-world situations on an ongoing basis.

AO International is addressing these limitations by introducing a comprehensive set of eLearning materials that extends and enhances

the current model. The AO Knowledge Services Portal offers surgeons a single entry point for their training. Education is now available 24 hours a day from any location with an Internet connection. Surgeons can learn at their own speed, during their spare time, or even between cases. The new content also offers a simplified way to earn CME credits.

With the launch of the AO Knowledge Services Portal this summer, the first phase of course content goes online. Three major strands will be offered:

- AO Briefings, which are 15 to 25-minute modules covering AO principles and operating techniques in a highly visual manner. Courses also include voice-over audio that guides the learner through the pertinent information.



AO Case Series: title screen.



AO Case Series: diagnosis screen.



AO Case Series: soft-tissue classification (schematic).



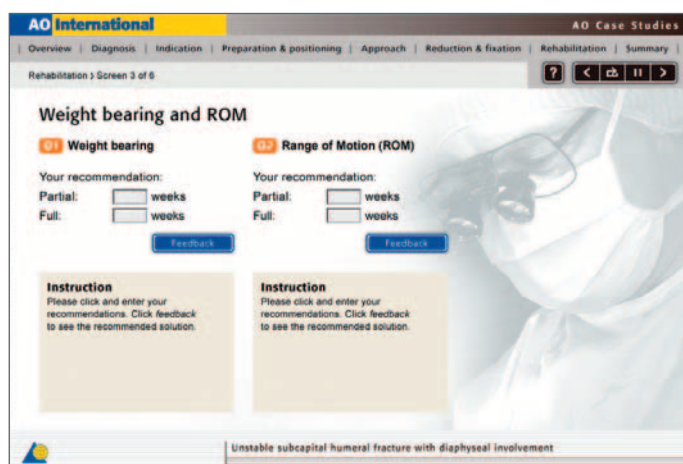
AO Case Series: interactive screen.



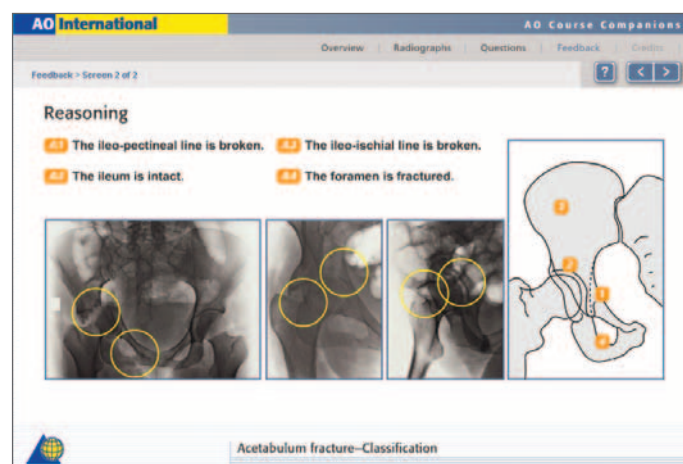
AO Case Series: approach screen.



AO Case Series: start of the operation screen.



AO Case Series: rehabilitation screen.



AO Course Companions: feedback screen.

- AO Case Studies, which are highly interactive 30- to 45-minute modules that aid surgeons in the decision-making process using actual clinical cases. The participant moves through the preoperative, operative, and postoperative processes and is prompted to make key decisions and recommend treatment options at each stage. At the end of each course, their selections are summarized, alongside the recommended solutions.
  - AO Course Companions, which are 5 to 10-minute modules designed to be used as precourse or postcourse tests. Learners can apply what they have learnt during an AO course, or can assess any gaps they may have in their knowledge.
- Future content will include detailed examinations of AO principles and strategies for treating specific fracture types. More advanced features of the AO Knowledge Services Portal will also be leveraged to create custom learning paths based on a participant's performance.
- While the initial rollout will feature courses in English, additional languages will follow shortly. The long-term plan calls for content adapted to cultural differences, as well as content tailored to areas of resource limitation, including courses in fracture care under restricted conditions.
- With the launch of the AO Knowledge Services Portal, AO Education now offers a complete blended learning environment that includes live classroom courses, textbooks, journals, CD-ROMs and now eLearning. AO Education aims to capture all levels of orthopedic surgeons, offering a truly life-long curriculum, accessible as part of a daily routine, ensuring that participants stay at the leading edge of orthopedic surgery.



Fabio Suárez, Jaime Quintero

## PORTRAIT OF CARLOS A SATIZÁBAL, MD

### **"A military pilot with AO ideas well on the ground"**

Col Carlos A Satizábal, MD, is a man of tradition, discipline, and duty. He earned his MD degree at the "Facultad de Medicina, Universidad Militar Nueva Granada" in Bogotá, Colombia in 1983. Immediately afterwards he was sent as a lieutenant to the "Escuela de Pilotos de la Fuerza Aérea" in Cali, and two years later he started his 4-year-training in orthopedics and traumatology at the "Departamento de Ortopedia y Traumatología, Hospital Militar Central" in Bogotá.

Once he had finished his residency he served for 2 years as "Instructor de Ortopedia" with an active practise in ER procedures, including politrauma, severe high-energy GSW, landmine injuries, and bone reconstruction procedures. In 1992 he attended as a visiting fellow the "Hospital de Nuestra Señora de Covadonga" in Oviedo, Asturias (Spain) and upon his return to Bogotá he dedicated himself totally to bone reconstructive surgery, including management of severe defects, complex nonunions, deformities, bone lengthening, and bone transport. He has attended first as participant and then as faculty several AO

Principles and Advanced Courses in Colombia and he was recently in Davos attending the Masters Course.

The "Hospital Militar Central" de Bogotá is an impressive University Hospital and the Centre "par excellence" in Colombia for the treatment of war injuries and their sequelae. With more than 300 beds, the "Departamento de Ortopedia y Traumatología" is one of the busiest trauma units in Colombia. 4,200 operating procedures are performed and more than 34,000 patients are seen in the various clinics every year: trauma, external fixation, hand and upper extremity, spine, hip, knee, foot and ankle, bone oncology, pediatrics, and rehabilitation.

In the late seventies Prof Dr Hans Willenegger visited the "Hospital Militar Central" and, after some hot discussions between the staff members, this centre became one of the "AO cradles" in Colombia. Quite interestingly, the first paper on "Ankle fractures, results after AO Fixation techniques" by one of the residents provoked such a debate during the National Meeting of the "Sociedad Colombiana de Cirugía Ortopédica y Traumatología, SCCOT" in the early eighties that the young resident was almost "crucified".

Col Dr Satizabal is considered a leading authority in complex bone reconstructive procedures. He has gained a well-known reputation in the use of external fixation in almost all modalities and techniques. He is a permanent guest in national and international conferences and has published several papers and a book chapter. He is currently Assistant Professor at the "Universidad Militar de Medicina" and the "Escuela de Medicina, Universidad Del Bosque". He has recently been discussing his novel ideas in external fixation with the ExFix Working Group and Synthes Lat. His contributions have led to several prototypes and new clamps being developed, which improve the modularity and extend the scope of the Tubular External Fixation in bone transport, complex deformities, and severe joint injuries.

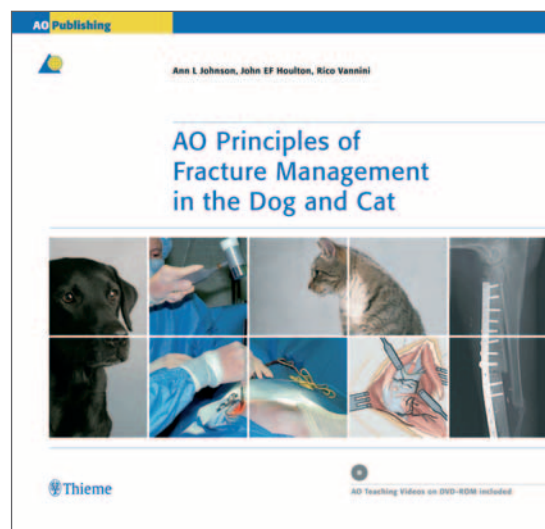


Carlos A Satizábal (left) and Roberto Masliah from Uruguay (right).

Col Carlos "el Gordo" Satizabal is now a full Colonel of the Air Force, where he is admired for his warm personality and good sense of humour. During his free time he likes to relax in his farm in La Vega, a small town near Bogotá, where he is surrounded by hundreds of music CD's. "El Gordo" is an avid collector of "salsa music" and from time to time he even tries one or two steps with his wife María, although their two children, Laura and Jose Antonio, always run away to the playground.

Renate Huter

## NEWS FROM AO PUBLISHING



### We are happy to announce our latest publication—the “AO Principles of Fracture Management in the Dog and Cat”.

This publication is primarily intended for small animal veterinary orthopedic surgeons, small animal orthopedic residents, and veterinary students.

The book is a complete source for the AO principles and methods of fracture management, principles of patient management, and description of procedures used to manage specific fractures in dogs and cats. The textbook is complemented by animations and sequences from AO Teaching Videos on a DVD-ROM.

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