



SonicWeld Rx[®]

The Perfect Choice



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

SonicWeld Rx®

It was back in 2001 when KLS Martin launched the osteosynthesis system Resorb x. Thus offering the first completely resorbable implants made of pure PDLLA. But this was just the beginning.

In 2005, KLS Martin proceeded to revolutionize the field of resorbable osteosynthesis by introducing SonicWeld Rx®, the unique ultrasound technology for insertion of SonicPins Rx®.

In 2013, a new chapter in the company's history of resorbables was opened by the introduction of Resorb xG, a PLLA-PGA polymer with improved mechanical features.

Now, KLS Martin is setting up another milestone: The second generation of SonicWeld Rx®. The novel device is an optical highlight in every OR, offering improved and additional features for a user-friendly application. Just see for yourself.

SonicWeld Rx®. The perfect choice.

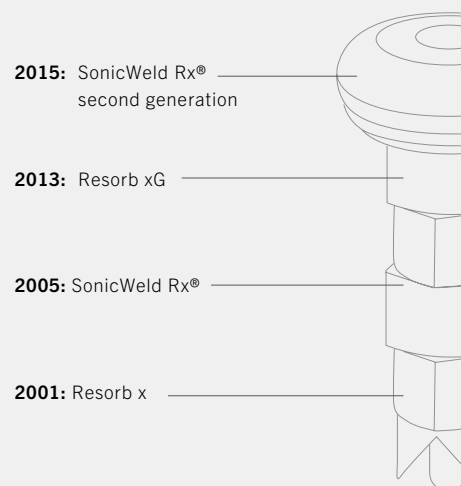
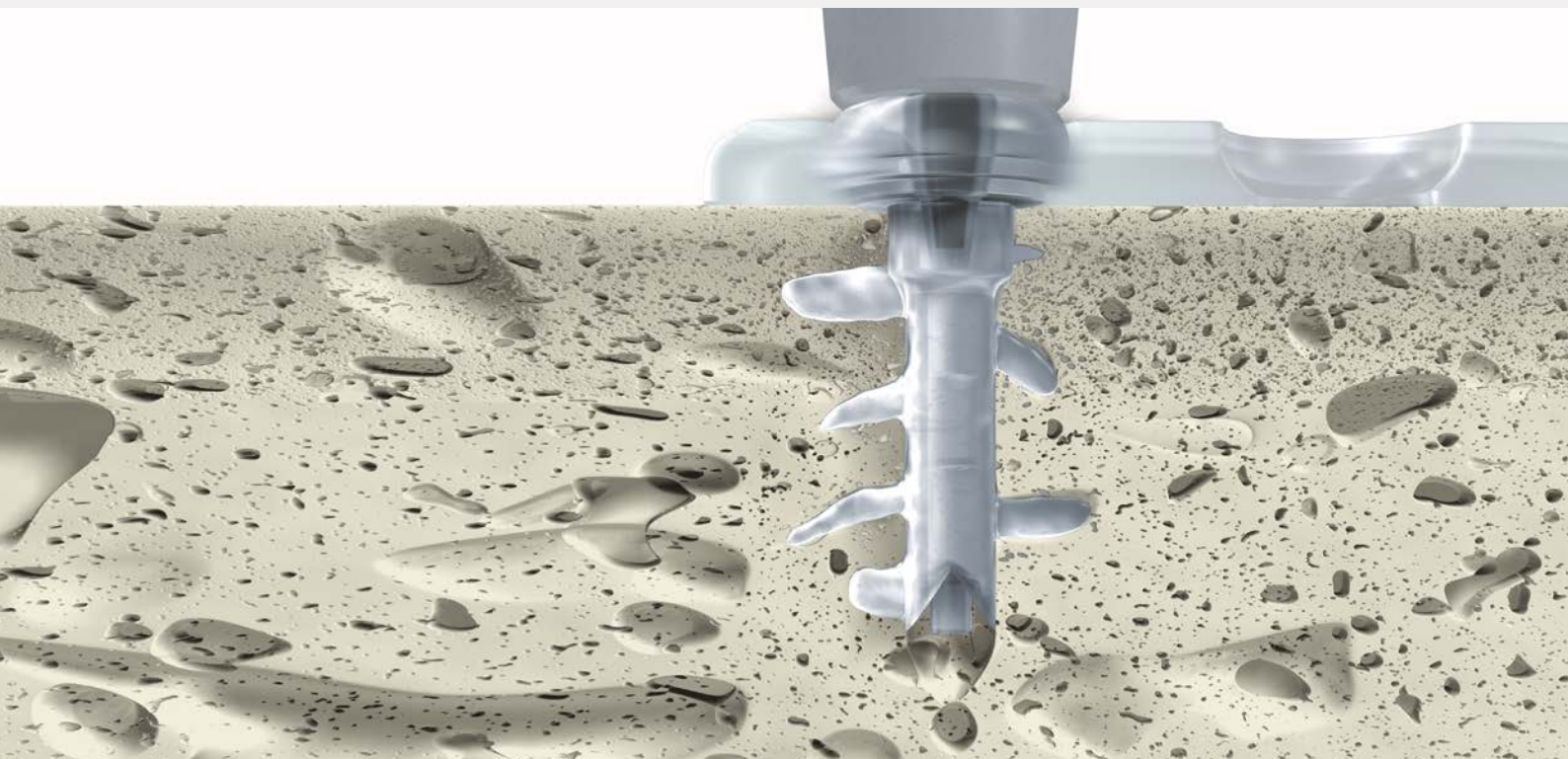




Table of Contents

	Pages
Feature, Function, Benefit	6 - 15
Indications	16 - 17
References	18 - 19

Feature, Function and Benefit



SonicWeld Rx® is a revolutionary technique for use in craniomaxillofacial osteosynthesis. It combines highly advanced ultrasound technology with resorbable implants to provide extremely stable fixation and 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 Rx® 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.

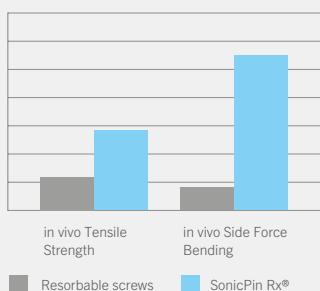
The method is clinically certified and validated and very patient-friendly as well. The implants degrade through natural hydrolysis in a controlled process. SonicWeld Rx® is primarily stable, convenient, fast, easy and safe. Designed for cranial fixation, ideal for pediatric trauma, and indicated also for cancellous bone structures.

Feature and Function

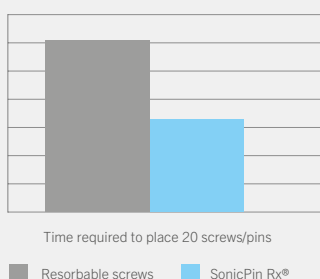
Benefit



- The ultrasonic energy sets the SonicPin Rx® into mechanical vibration
- The liquid SonicPin Rx® penetrates into the bone cavities
- The principle works both in cortical and cancellous spongy bone
- Low power effort during SonicPin Rx® insertion
- Implantation of the SonicPin Rx® in angle position is possible
- Maximum temperature increase of the bone at about 1 mm from the implant: 11 °C
- Only 30 - 40 seconds after SonicPin Rx® insertion, temperature increase is below 5 °C
- No risk of pin/screw breakage
- The material liquifies at the interface between the pre-drilled bone and the SonicPin Rx® via friction
- The material reaches bone cavities beyond the reach of common screws
- Excellent three-dimensional stability both in cortical and spongy bone
- Particularly effective in poorer bone quality
- Repositioning of small bone fragments
- Especially suitable in cramped corners without dislocation
- Maximum bone temperature is below denaturing temperature of 56 °C
- No bone necrosis
- Fast cooling down of the material and surrounding bone
- Secure anchorage of the SonicPin Rx® in the bone only three seconds after activation
- No emergency system is necessary



- Locking effect between the SonicPin Rx® and the pre-drilled hole
- Locking effect between the SonicPin Rx® head and the plate
- Locking mechanism can be reversed by drilling through the inserted SonicPin Rx®
- Due to the double locking mechanism extremely stable fixation of the SonicPin Rx® in the pre-drilled hole
- With SonicPins Rx® twice the strength compared to resorbable screws can be achieved
- Simple implant removal
- Simple correction of the implant position



- No need for pre-tapping
- Exceptionally fast implantation of the SonicPin Rx®
- Reduction in surgical time

Feature, Function and Benefit



Two resorbable polymers for osteosynthesis, PDLLA and PLLA-PGA, have been well-established in craniomaxillofacial surgery.

Resorb x® polymer is a 100% Poly-D,L-Lactic Acid (PDLLA).

Resorb xG polymer consists of 85% Poly-L-Lactic Acid (PLLA) and 15% Poly Glycolic Acid (PGA).

Both resorbables maintain the majority of their strength for 8-10 weeks, allowing complete fracture healing and bone regeneration.

The core of the degradation process:

The complex polymer chains absorb the water contents (H₂O molecules) of surrounding body fluids through a process called “hydrolysis”.

The stored water initiates the degradation process by continuously breaking down the long polymer chains into ever shorter structures or simpler molecules. Metabolic pathways subsequently transform the molecules into carbon dioxide and water; both of these compounds are discharged naturally.

SonicWeld Rx[®]

Resorb x

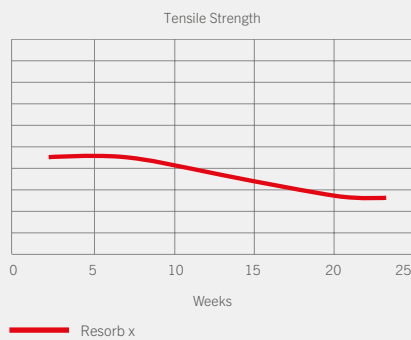
Feature and Function

Benefit



- Polymer consists of 100% Poly-D,L-Lactic Acid (PDLLA)

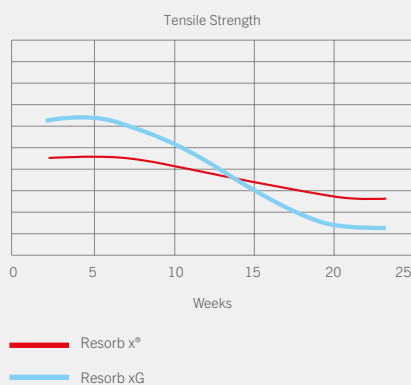
- Totally amorphous polymer
- Residue free degradation
- Numerous animal and clinical studies prove excellent biocompatibility and a safe degradation process.
- Resorption time observed in ultrasound follow-up: 12 - 30 months



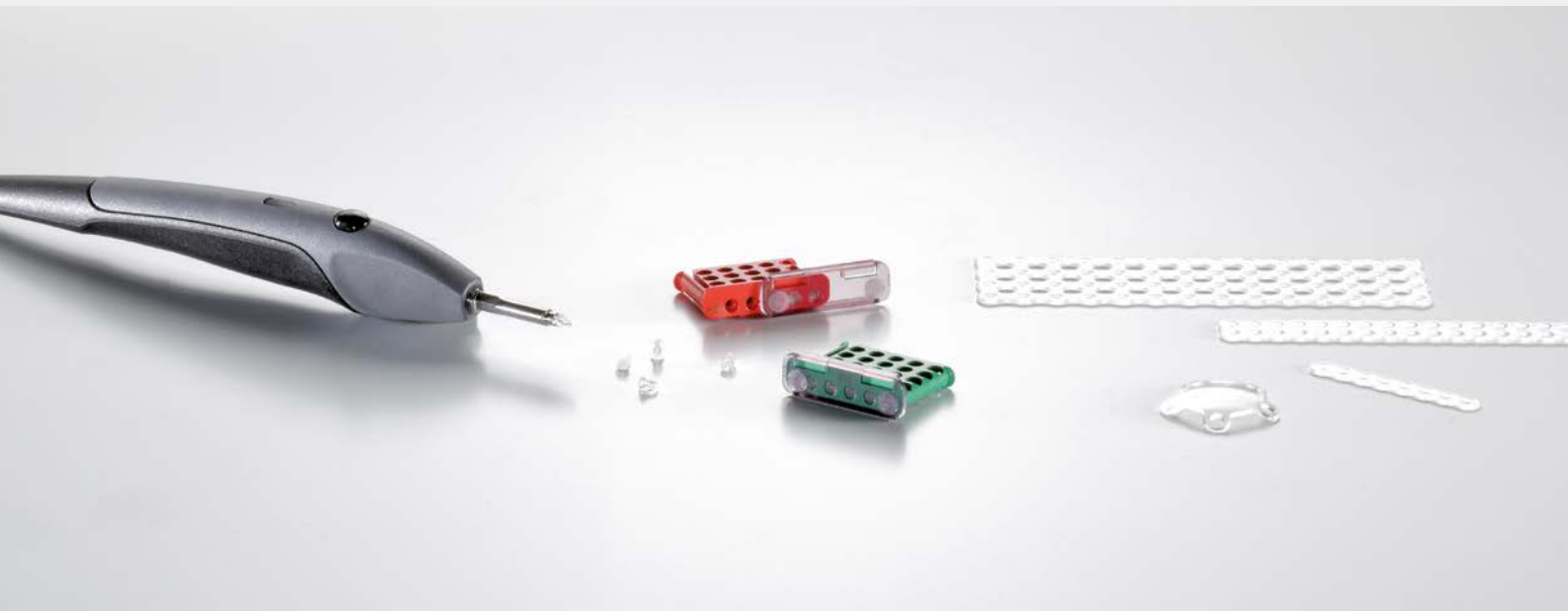
Resorb xG

- Polymer consists of 85% Poly-L-Lactic Acid (PLLA) and 15% Poly Glycolic Acid (PGA)

- Higher initial strength
- Faster decrease of both strength and mass
- Resorption time: approximately 12 - 14 months



Feature, Function and Benefit



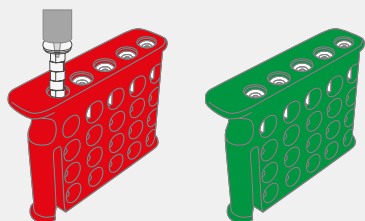
SonicPins Rx® are characterized by their unique geometry. The geometry guarantees maximum polymer outflow in the surrounding bone cavities during SonicPin Rx® insertion. Thus reducing the power effort for SonicPin Rx® insertion to a minimum. Sonic Pins Rx® are available in two diameters:

- **green clip:** Ø 1.6 mm
- **red clip:** Ø 2.1 mm

Resorbable implants are available in various designs and thicknesses to give the surgeon options to match every indication. The holes of the plates and meshes are perfectly adapted to the geometry of the SonicPins Rx®. Thus the head of the SonicPin Rx® is optimally countersunk in the implant.

SonicWeld Rx®

SonicPins Rx®



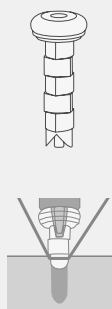
Feature and Function

- Color-coded clip magazines
 - green: SonicPins Rx® Ø 1.6 mm
 - red: SonicPins Rx® Ø 2.1 mm
- Self-retaining pin head
- Optimized pin geometry
- Both SonicPin Rx® sizes fit all implants of Resorb x and Resorb xG product range
- Sterile delivery

Benefit

- Easy identification of the appropriate SonicPin diameter
- Convenient pin removal from clip magazine
- Maximum polymer outflow in the surrounding bone structure
- Easy pin insertion
- Complete cross compatibility
- Always ready to use

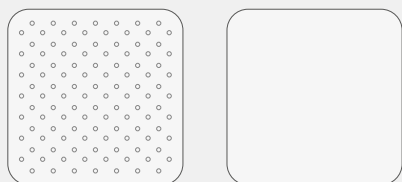
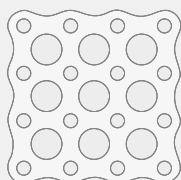
SonicPin Rx® types



- Standard SonicPin Rx®
- Micro SonicPins Rx® without pin head
- Endobrow SonicPins Rx® with specially designed pin tip for sutures

- Perfect solution for a wide range of applications
- Ideal for narrow spaces, e. g. preprosthetic augmentation
- Ideal for endobrow lifting

Plates, Meshes, Foils and Membranes



- Huge variety of different geometries, sizes and thicknesses
- Round edge geometry
- Can easily be contoured in the Xcelsior water bath and cut with scissors intraoperatively
- Flexible meshes
- Membranes and foils with minimal thickness (0.1, 0.2 or 0.3 mm)
- All Resorb x and Resorb xG implants fit both SonicPin diameters (1.6 and 2.1 mm)
- Sterile delivery

- Right implant for every indication
- Minimal palpability and susceptibility
- Easy adaption to patient-specific anatomy
- Very easy to adapt to patient specific anatomy
- Ideal for preprosthetic augmentation
- Complete cross compatibility
- Always ready to use

Feature, Function and Benefit

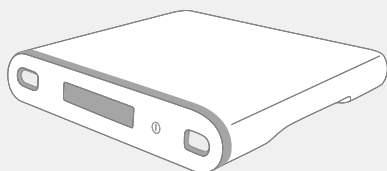


The ultrasonic unit of the SonicWeld Rx® system converts electric energy into mechanical vibrations (ultrasound).

When using a standard sonotrode, the ultrasonic energy causes a phase change of the resorbable material at the interfaces between the bone and the SonicPins Rx® via friction. Thus the SonicPin Rx® glides into the predrilled hole. When using a smoothing sonotrode, the ultrasonic energy allows to smooth the resorbable implants (e. g. a membrane).

SonicWeld Rx®

Ultrasonic unit



Feature and Function

- Simple and elegant design
- Round edge geometry
- Two handles to carry the device
- Two connecting sockets for handpieces
- One pre-defined power level
- Opportunity to choose the individual system language

Benefit

- Clear optical distinction to first generation device
- Easy to clean
- Secure fit of the device during transportation
- Possibility to work alternatingly with two sonotrodes (e.g. a standard and a smoothing sonotrode or two standard sonotrodes)
- Optimal system setting
- User-friendly application
- No comprehensive problems

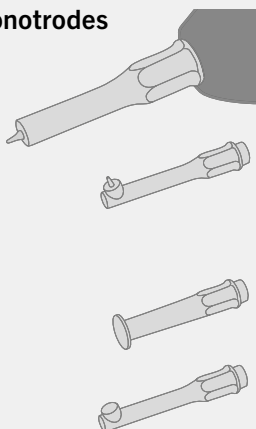
Handpiece



- Ergonomically designed handpiece
- Finger activation
- Light and acoustic support during activation
- Autoclavable

- Well balanced and comfortable fit
- Exclusive concentration on the hand during SonicPin Rx® insertion or smooting
- 1:1 feedback during activation period
- Guaranteed biocompatibility for 250 sterilization cycles

Sonotrodes



- Standard sonotrodes
 - straight
 - angled
- Smoothing sonotrodes
 - straight
 - angled

- Ideal for SonicPin Rx® insertion in straight position
- Combined sonotrode
Ideal for SonicPin Rx® insertion in angled position (e. g. orbita or side tooth area)
- Smoothing of implants in straight position
- Smoothing of implants in straight or angled position (e. g. orbita or side tooth area)

Feature, Function and Benefit

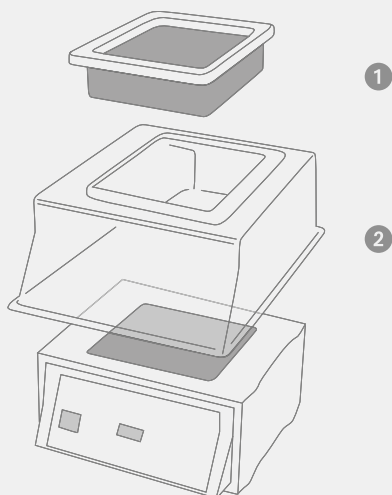


The Xcelsior water bath is intended for heating up resorbable implants for the purpose of adapting them to the patient's anatomical conditions (e. g. bone surface). Various templates are available that help to adapt the implants to the shape of the bone.

The BOS drill is a fully-fledged and universally applicable drill system. The battery tools do not require a charger or base unit and are always ready – wherever and whenever you need them.

SonicWeld Rx®

Xcelsior water bath



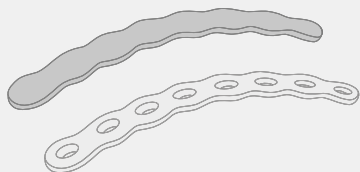
Feature and Function

- Tool for heating up Resorb x and Resorb xG implants in the hot water (70 - 90 °C / 158 - 194 °F) to adapt it to the patient-specific bone contour
- Sterilizable material ① ②

Benefit

- Perfect temperature range to adapt Resorb x and Resorb xG implants
- To be used in the sterile area of the OR

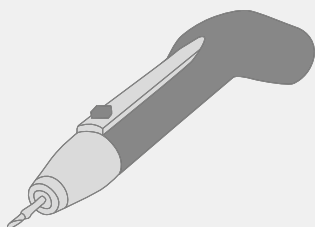
Templates



- Various templates available
- Adaption of the implant to the patient's anatomical condition in the Xcelsior water bath

- Template reflects the implant 1-to-1
- Safe selection of the sterile-packed implant
- Perfect fit of implant

BOS Drill



- 600 rev/min, high-speed forward
- Ergonomic design
- Lightweight handle weighing only 200 g
- Can be operated with a finger
- Sterile battery pack simply needs to be clicked-on

- Ideal for predrilling
- Safe fit in the user's hand
- Especially indispensable when dealing with a large number of implants
- Comfortable to use
- Always charged and ready for use

Step by Step to innovative Osteosynthesis

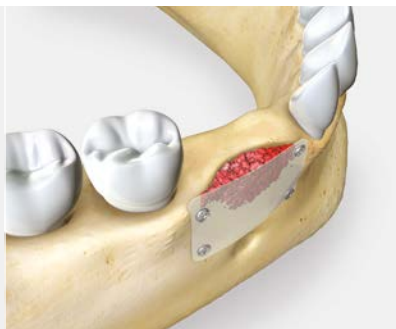


Indications

The KLS Martin Resorb x and Resorb xG implants are intended for surgical procedures in which an internal fixation by resorbable implants is required for aligning, reconstructing and stabilizing bone tissue.



Craniofacial corrective
osteotomies
(e. g. craniosynostosis)



Osteosynthesis in non-load-bearing areas of the craniomaxillofacial skeleton

Preprosthetic augmentation

Endobrow fixation

Literature

- Abdel-Galil, K. & Loukota, R.,
Fixation of comminuted diacapitular fractures of the mandibular condyle with ultrasound-activated resorbable pins.
Br J Oral Maxillofac Surg, 46(6), 2008, S. 482-484
- Aldana, P. R., et al.,
Ultrasound-aided fixation of a biodegradable cranial fixation system: uses in pediatric neurosurgery.
J Neurosurg Pediatr, 3(5), 2009, S. 420-424
- Aldana, P. R., et al.,
Ultrasound-aided fixation of biodegradable implants in pediatric craniofacial surgery.
Pediatr Neurosurg, 47(5), 2011, S. 349-353
- Arnaud, E. & Renier, D.,
Pediatric craniofacial osteosynthesis and distraction using an ultrasonic-assisted pinned resorbable system: a prospective report with a minimum 30 months' follow-up.
J Craniofac Surg, 20(6), 2009, S. 2081-2086
- Basa, S.,
Does ultrasonic resorbable pin fixation offer predictable results for augmentation eminoplasty in recurrent dislocations?
J Oral Maxillofac Surg, 72(8), 2014, S. 1468-1474
- Buijs, G. J., et al.,
Mechanical strength and stiffness of the biodegradable SonicWeld Rx® osteofixation system.
J Oral Maxillofac Surg, 67(4), 2009, S. 782-787
- Burger B. W.,
Use of ultrasound-activated resorbable poly-D, L-lactide pins (SonicPins) and foil panels (Resorb x®) for horizontal bone augmentation of the maxillary and mandibular alveolar ridges.
J Oral Maxillofac Surg, 68(7), 2010, S. 1656-1661
- Chen, Y. B. & Zhang, H. Z.,
Ultrasound-aided biodegradable osteosynthesis system: application in fixation of oral and maxillofacial fractures.
Zhonghua Yi Xue Za Zhi, 93(18), 2013, S. 1418-1421
- Cho P. W. J., et al.,
Biomechanical study of SonicWeld Rx® pin in cortical bone graft layering technique.
J Oral Maxillofac Surg, 69(5), 2011, S. 1519-1524
- Cristofaro, M. G., et al.,
A new system of resorbable rigid three-dimensional fixation using ultrasound (SonicWeld Rx®+ Sonic Pins Rx) adopted in craniofacial traumatology: the author's experience.
It J Maxillofac Surg, 20, 2009, S. 4-52
- Eckelt U., et al.,
Ultrasound aided pin fixation of biodegradable osteosynthetic materials in cranioplasty for infants with craniosynostosis.
J Craniomaxillofac Surg, 35(4-5), 2007, S. 218-221
- Heidemann W., et al.,
Degradation of poly(D,L)lactide implants with or without addition of calciumphosphates in vivo.
Biomaterials, 22(17), 2001, S. 2371-2381
- Heidemann W. & Gerlach K. L.,
Sonographic examinations on the degradation of bioresorbable osteosynthesis materials.
Biomed Tech, 46(9), 2001, S. 236-240
- Heidemann W, et al.,
In vivo investigation of the degradation of poly(D,L)lactide and poly(L-lactide-co-glycolide) osteosynthesis material.
Mand-, Kiefer- GesichtsChir, 7, 2003, S. 283-288
- Iglhaut, G.,
The Minimally Invasive Shell Technique for Bone Augmentation.
Oralchirurgie Journal, 9(3), 2009
- Iglhaut, G., et al.,
Shell technique using a rigid resorbable barrier system for localized alveolar ridge augmentation.
Clin Oral Implants Res, 25(2), 2014, S. 149 - 154

- Lee, J. H. & Park, J. H.,
The clinical usefulness of ultrasound-aided fixation using an absorbable plate system in patients with zygomatico-maxillary fracture.
Arch Plast Surg, 40(4), 2013, S. 330-334
- Mai, R.,
Bone welding – a histological evaluation in the jaw.
Ann Anat, 189(4), 2007, S. 350-355
- Meara, D. J., et al.,
Fixation of Le Fort I osteotomies with poly-DL-lactic acid mesh and ultrasonic welding – a new technique.
J Oral Maxillofac Surg, 70(5), 2012, S. 1139-1144
- Müller-Richter, U. D., et al.,
Treatment of intracapsular condylar fractures with resorbable pins.
J Oral Maxillofac Surg, 69(12), 2011, S. 3019-3025
- Pietrzak W.S.,
Bioabsorbable polymer applications in musculoskeletal fixation and healing.
In: Pietrzak W. S. (ed.), Orthopedic biology and medicine: Musculoskeletal tissue regeneration, biological materials and methods,
Totawa: Humana Press, 2008, S. 509-529
- Pilling E., et al.,
An Experimental study of the biomechanical stability of ultrasound-activated pinned (SonicWeld Rx® + Resorb x®) and screwed fixed (Resorb x®) resorbable materials for osteosynthesis in the treatment of simulated craniosynostosis in sheep.
Br J Oral Maxillofac Surg, 45(6), 2007, S. 451-456
- Pilling, E., et al.,
An experimental in vivo analysis of the resorption to ultrasound-activated pins (SonicWeld Rx®) and standard biodegradable screws (Resorb x®) in sheep.
Br J Oral Maxillofac Surg, 45(6), 2007, S. 447-450
- Reichwein, A.,
Clinical experiences with resorbable ultrasonic-guided, angle-stable osteosynthesis in the panfacial region.
J Oral Maxillofacial Surg, 67(6), 2009, S. 1211-1217
- Schneider, M., et al.,
Stability of fixation of diacapitular fractures of the mandibular condylar process by ultrasound-aided resorbable pins (SonicWeld Rx® System) in pigs.
Br J Oral Maxillofac Surg, 49(4), S. 297-301
- Schneider, M., et al.,
Ultrasound-aided resorbable osteosynthesis of fractures of the mandibular condylar base: an experimental study in sheep.
Br J Oral Maxillofac Surg, 50(6), 2012, S. 528-532
- Stelnicki, E. J., et al.,
Use of absorbable poly (D,L) lactic acid plates in cranial-vault remodeling: presentation of the first case and lessons learned about its use.
Cleft Palate Craniofac J, 42(4), 2005, S. 333-339
- Völker, W., et al.,
The use of resorbable osteosynthesis materials.
Laryngorhinootologie. 90(1), 2011, S. 23-25
- Wood, R. J., et al.,
New resorbable plate and screw system in pediatric craniofacial surgery.
J Craniofac Surg, 23(3), 2012, S. 845-849

KLS Martin Group

KLS Martin Australia Pty Ltd.

Sydney · Australia
Tel. +61 2 9439 5316
australia@klsmartin.com

KLS Martin do Brasil Ltda.

São Paulo · Brazil
Tel. +55 11 3554 2299
brazil@klsmartin.com

KLS Martin Medical (Shanghai) International Trading Co., Ltd

Shanghai · China
Tel. +86 21 5820 6251
info@klsmartin.com

KLS Martin India Pvt Ltd.

Chennai · India
Tel. +91 44 66 442 300
india@klsmartin.com

KLS Martin Italia S.r.l.

Milan · Italy
Tel. +39 039 605 67 31
info@klsmartin.com

KLS Martin Japan K.K.

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

KLS Martin SE Asia Sdn. Bhd.

Penang · Malaysia
Tel. +604 261 7060
malaysia@klsmartin.com

KLS Martin de México, S.A. de C.V.

Mexico City · Mexico
Tel. +52 55 7572 0944
mexico@klsmartin.com

KLS Martin Nederland B.V.

Huizen · Netherlands
Tel. +31 35 523 45 38
infonl@klsmartin.com

KLS Martin SE & Co. KG

Moscow · Russia
Tel. +7 499 792 76 19
russia@klsmartin.com

KLS Martin Taiwan Ltd.

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

KLS Martin SE & Co. KG

Dubai · United Arab Emirates
Tel. +971 4 454 16 55
middleeast@klsmartin.com

KLS Martin UK Ltd.

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

KLS Martin LP

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

KLS Martin SE Asia Sdn. Bhd.

Hanoi · Vietnam
Tel. +49 7461 706-0
info@klsmartin.com



KLS Martin SE & Co. KG

A company of the KLS Martin Group

KLS Martin Platz 1 · 78532 Tuttlingen · Germany
PO Box 60 · 78501 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com

