Craniomaxillofacial Surgery



SonicWeld Rx®

The Perfect Choice





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

Congenital facial deformities put individuals at a severe disadvantage not only in terms of outward appearance, but functionally too because severe loss of function is a frequent side-effect of such conditions. Of course, acquired defects can have similar consequences as well. Given the anatomical complexities of the cranial and facial structures, reconstruction and correction require a sort of specialization that fits into the broader context. But that's not all - because successful treatment wouldn't be possible without the availability of high-precision and reliable products.

KLS Martin is one of the globally leading suppliers in the field of craniomaxillofacial surgery. Our product portfolio offers you everything you need for advanced osteosynthesis and distraction. This implies that you get more than just standard products. We are always ready to develop patient-specific solutions wherever the need arises.

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SonicWeld Rx®

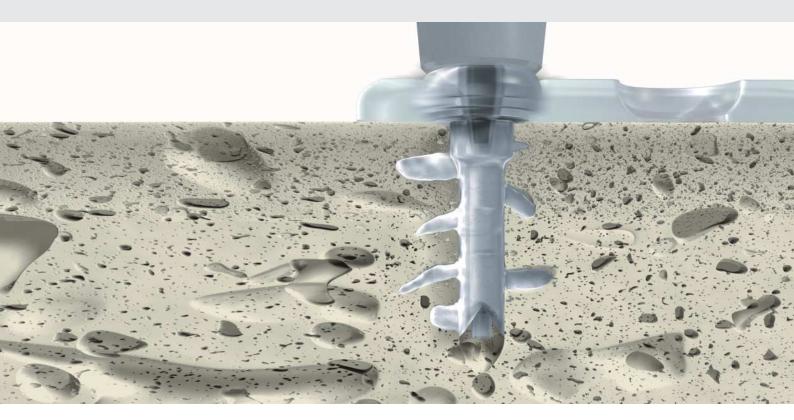
It was back in 2001 when KLS Martin launched the osteosynthesis system Resorb x° . Thus offering the first completely resorbable implants made of pure PDLLA. But this was just the beginning.

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

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.



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 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.

Sonic Weld Rx®

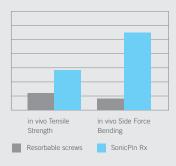




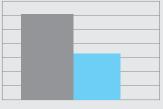
Feature and Function

- The ultrasonic energy sets the SonicPin into mechanical vibration
- The liquid SonicPin penetrates into the bone cavities
- The principle works both in cortical and cancellous spongious bone
- Low power effort during SonicPin insertion
- Implantation of the SonicPin 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 insertion, temperature increase is below 5 °C
- No risk of pin/screw breakage

- Benefit
- The material liquifies at the interface between the pre-drilled bone and the SonicPin via friction
- The material reaches bone cavities beyond the reach of common screws
- Excellent three-dimensional stability both in cortical and spongious 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 in the bone only three seconds after activation
- No emergency system is necessary



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

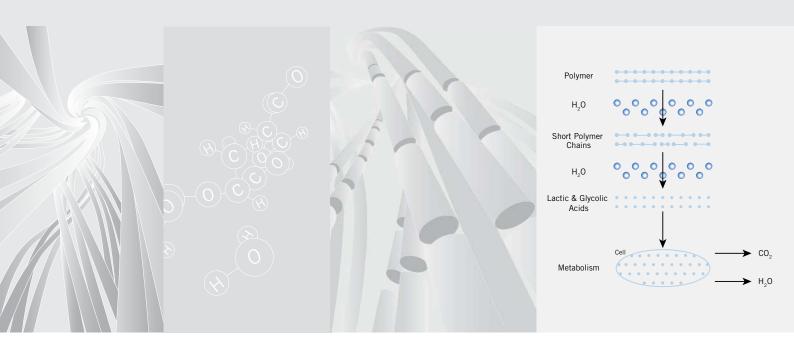


Time required to place 20 screws/pins

Resorbable screws SonicPin Rx

No need for pre-tapping

- Exceptionally fast implantation of the SonicPin
- Reduction in surgical time



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 (H_2O 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.

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

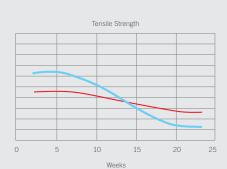
Tensile Strength 0 5 10 15 20 25 Weeks

Resorb xG

Resorb x®

Polymer consists of85% Poly-L-Lactic Acid (PLLA) and15% Poly Glycolic Acid (PGA)

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







SonicPins are characterized by their unique geometry. The geometry guarantees maximum polymer outflow in the surrounding bone cavities during SonicPin insertion. Thus reducing the power effort for SonicPin insertion to a minimum. Sonic Pins 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. Thus the head of the SonicPin is optimally countersunk in the implant.

SonicPins Feature and Function Benefit Color-coded clip magazines Easy identification of the appropriate ■ green: SonicPins Ø 1.6 mm SonicPin diameter ■ red: SonicPins Ø 2.1 mm Self-retaining pin head Convenient pin removal from clip magazine Optimized pin geometry Maximum polymer outflow in the surrounding bone structure Easy pin insertion Both SonicPin sizes fit all implants Complete cross compatibility of Resorb x® and Resorb xG product range Sterile delivery Always ready to use SonicPin types Standard SonicPin Perfect solution for a wide range of applications Micro SonicPins Rx without pin head Ideal for narrow spaces, e. g. preprosthetic augmentation Endobrow SonicPins Rx with specially Ideal for endobrow lifting designed pin tip for sutures Plates, Meshes, Foils and Membranes Huge variety of different geometies, Right implant for every indication sizes and thicknesses Round edge geometry Minimal palpability and susceptibility Can easily be contoured in the Xcelsior water Easy adaption to patient-specific bath and cut with scissors intraoperatively anatomy Flexible meshes Very easy to adapt to patient specific anatomy Membranes and foils with minimal Ideal for preprosthetic augmentation thickness (0.1, 0.2 or 0.3 mm) All Resorb x[®] and Resorb xG implants fit Complete cross compatibility both SonicPin diameters (1.6 and 2.1 mm)

Sterile delivery

Always ready to use



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 via friction. Thus the SonicPin glides into the predrilled hole. When using a smoothing sonotrode, the ultrasonic energy allows to smooth the resorbable implants (e. g. a membrane).

Sonic Weld Rx [®]		
Ultrasonic unit	Feature and Function	Benefit
	■ Simple and elegant design	 Clear optical distinction to first generation device
	Round edge geometry	Easy to clean
	Two handles to carry the device	 Secure fit of the device during transportation
	Two connecting sockets for handpieces	 Possibility to work alternatingly with two sonotrodes (e.g. a standard and a smoothing sonotrode or two standard sonotrodes)
	 One pre-defined power level 	Optimal system settingUser-friendly application
	 Opportunity to choose the individual system language 	 No comprehensive problems
Handpiece		
	Ergonomically designed handpiece	 Well balanced and comfortable fit
	■ Finger activation	 Exclusive concentration on the hand during SonicPin insertion or smooting
	 Light and acoustic support during activation 	■ 1:1 feedback during activation period
	Autoclavable	 Guaranteed biocompatibility for 250 sterilization cycles
Sonotrodes		
	Standard sonotrodes	
	■ straight	 Ideal for SonicPin insertion in straight position
	angled	 Combined sonotrode Ideal for SonicPin insertion in angled position (e. g. orbita or side tooth area)



- Smoothing sonotrodes
 - straight
 - angled

- Smoothing of implants in straight position
- Smoothing of implants in straight or angled position (e. g. orbita or side tooth area)



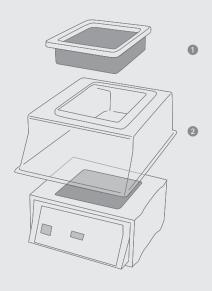
The Xcelsior water bath is intended for heating up resorbable implants for the purpose of adapting them to the patient's anatomical conditions (e. g. bone surface). Various templates are available that help to adapt the implants to the shape of the bone.

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.

Xcelsior water bath

Feature and Function

Benefit



- 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

- 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

- Safe selection of the sterile-packed
- implant

■ Template reflects the implant 1-to-1

Perfect fit of implant

BOS Drill



- 600 rev/min, high-speed forward
- Ergonomic design

water bath

- 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 x° 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

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