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SonicWeld Rx®

The Perfect Choice

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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.

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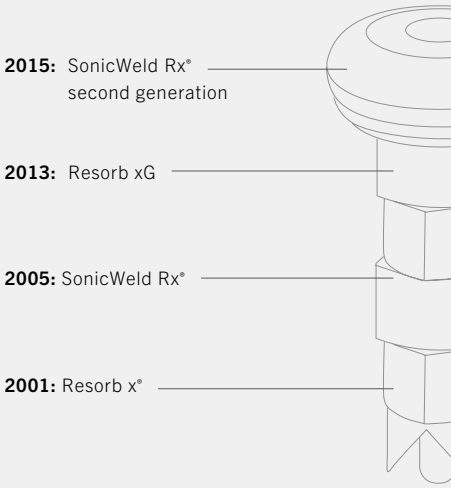
SonicWeld Rx®



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.

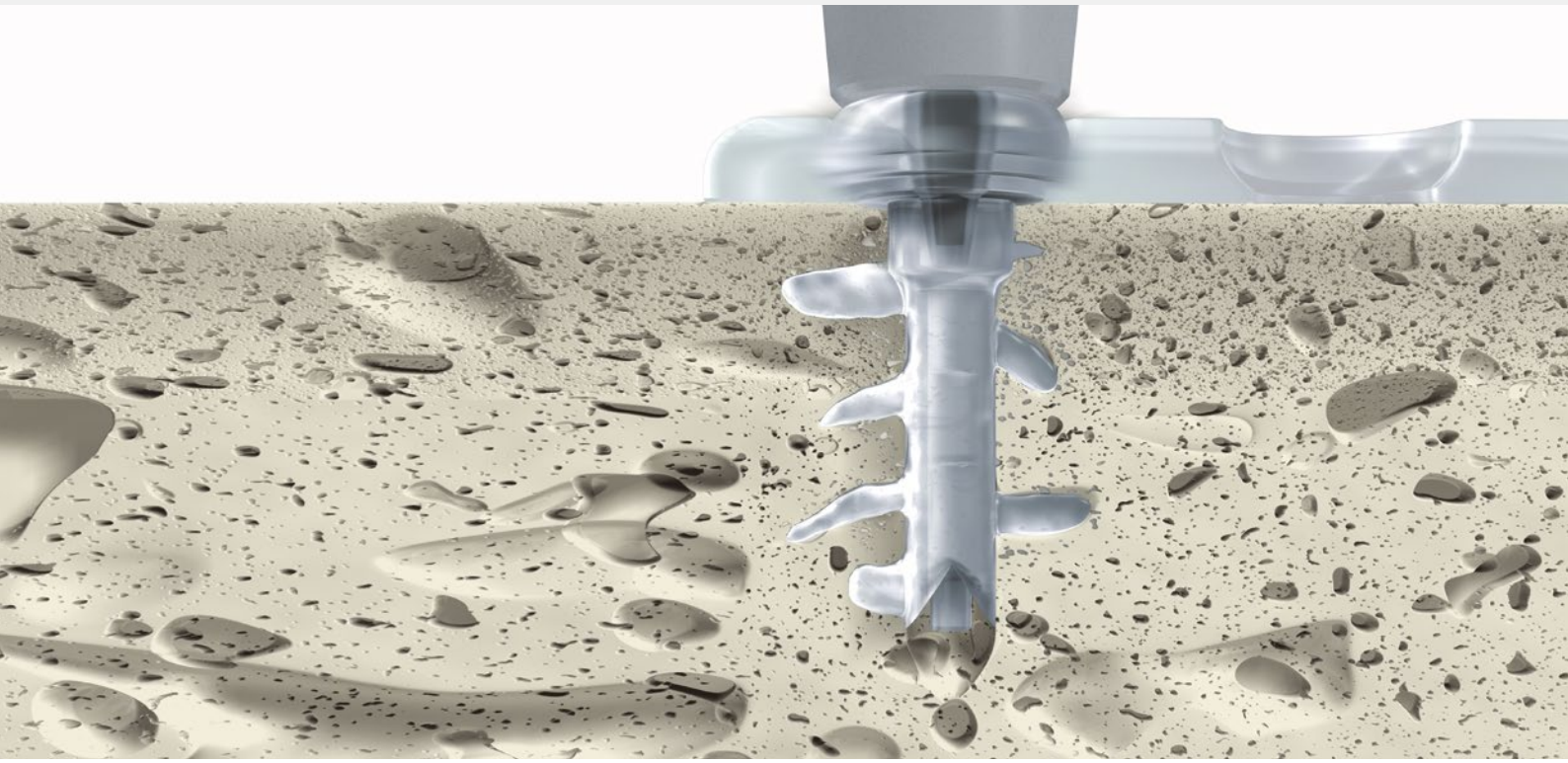
In 2005, KLS Martin proceeded to revolutionize the field of resorbable osteosynthesis by introducing SonicWeld Rx®, the unique ultrasound technology for insertion of SonicPins.

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.

Feature, Function and Benefit

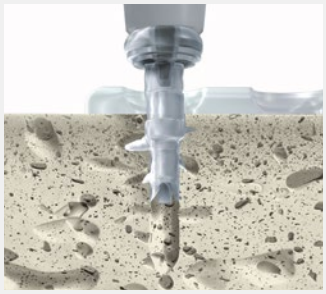
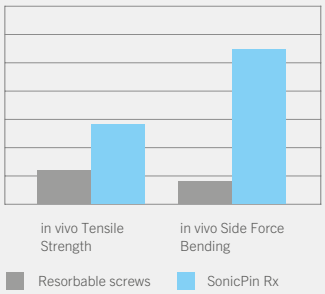
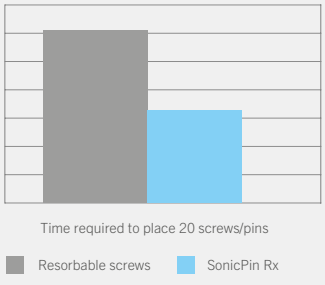


SonicWeld Rx® is a revolutionary technique for use in craniomaxillofacial osteosynthesis. It combines highly advanced ultrasound technology with resorbable implants to provide extremely stable fixation and completely eliminate the need for a second operation.

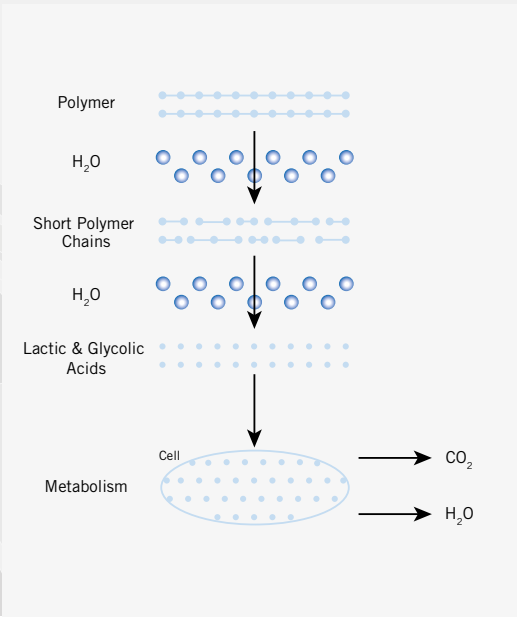
The procedure is simple: resorbable meshes are heated up, shaped to fit the application site and then fixed in place with SonicPins inserted into predrilled holes. This is done with a sonotrode that liquefies the pins, thus causing them to bond with the meshes and penetrate into the bone cavities to 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.

SonicWeld Rx®

	Feature and Function	Benefit
	■ The ultrasonic energy sets the SonicPin into mechanical vibration	■ The material liquifies at the interface between the pre-drilled bone and the SonicPin via friction
	■ The liquid SonicPin penetrates into the bone cavities	■ The material reaches bone cavities beyond the reach of common screws
	■ The principle works both in cortical and cancellous spongious bone	■ Excellent three-dimensional stability both in cortical and spongious bone
	■ Low power effort during SonicPin insertion	■ Particularly effective in poorer bone quality ■ Repositioning of small bone fragments
	■ Implantation of the SonicPin in angle position is possible	■ Especially suitable in cramped corners without dislocation
	■ Maximum temperature increase of the bone at about 1 mm from the implant: 11 °C	■ Maximum bone temperature is below denaturing temperature of 56 °C ■ No bone necrosis
	■ Only 30 - 40 seconds after SonicPin insertion, temperature increase is below 5 °C	■ Fast cooling down of the material and surrounding bone ■ Secure anchorage of the SonicPin in the bone only three seconds after activation
	■ No risk of pin/screw breakage	■ No emergency system is necessary
	■ Locking effect between the SonicPin and the pre-drilled hole	■ Due to the double locking mechanism extremely stable fixation of the SonicPin in the pre-drilled hole
	■ Locking effect between the SonicPin head and the plate	■ With SonicPins twice the strength compared to resorbable screws can be achieved
	■ Locking mechanism can be reversed by drilling through the inserted SonicPin	■ Simple implant removal ■ Simple correction of the implant position
	■ No need for pre-tapping	■ Exceptionally fast implantation of the SonicPin ■ 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).

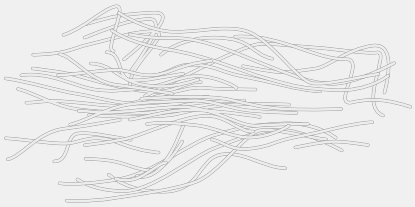
Resorb xG polymer consists of 85% Poly-L-Lactic Acid (PLLA) and 15% Poly Glycolic Acid (PGA).

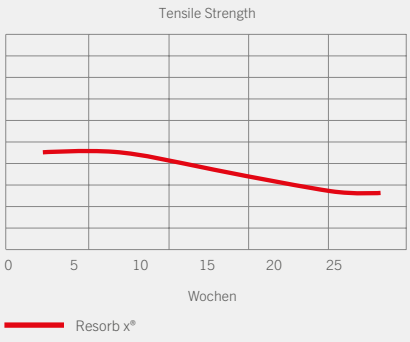
Both resorbables maintain the majority of their strength for 8-10 weeks, allowing complete fracture healing and bone regeneration.

The core of the degradation process:
The complex polymer chains absorb the water contents (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.

SonicWeld Rx®

Resorb x®





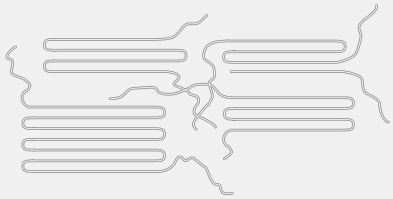
Feature and Function

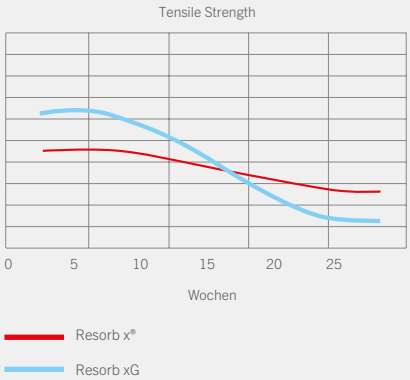
- Polymer consists of 100% Poly-D,L-Lactic Acid (PDLLA)

Benefit

- 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

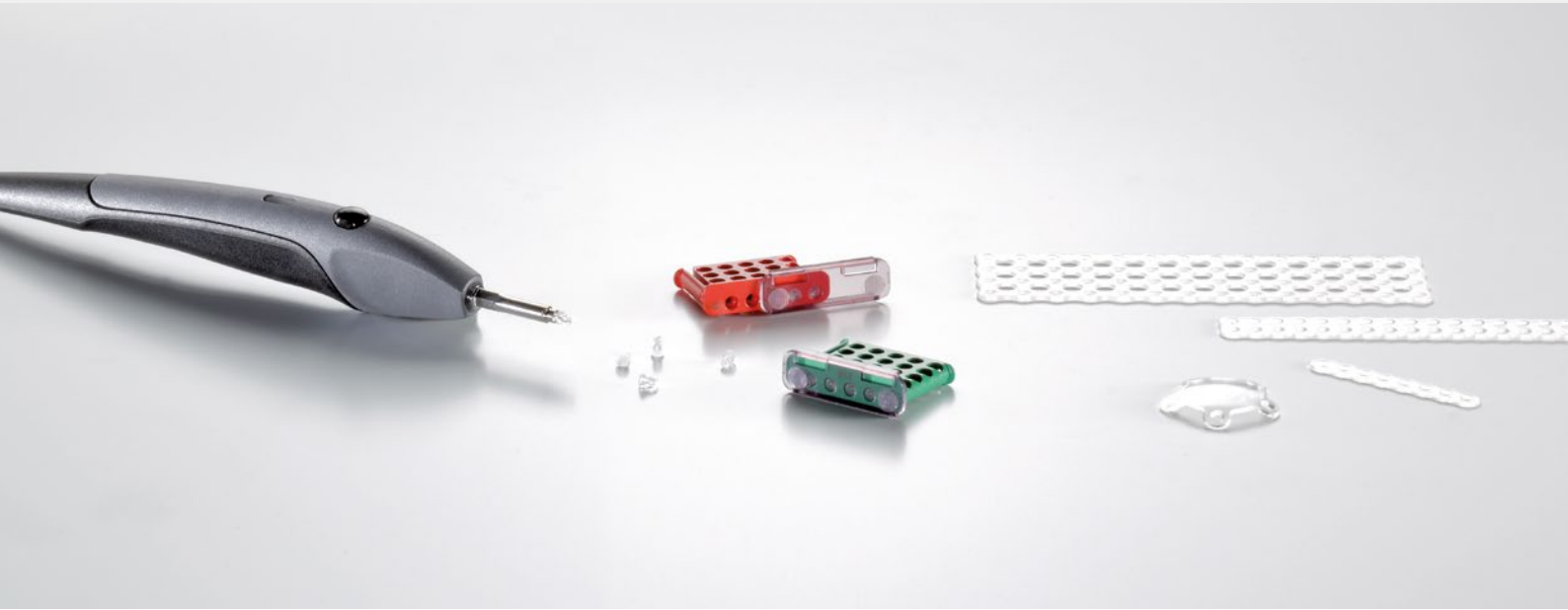




- Polymer consists of 85% Poly-L-Lactic Acid (PLLA) and 15% Poly Glycolic Acid (PGA)

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

Feature, Function and Benefit

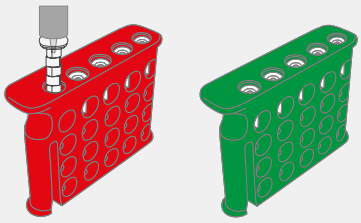


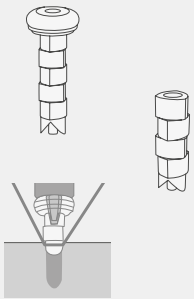
SonicPins are characterized by their unique geometry. The geometry guarantees maximum polymer outflow in the surrounding bone cavities during SonicPin insertion. Thus reducing the power effort for SonicPin insertion to a minimum. Sonic Pins are available in two diameters:

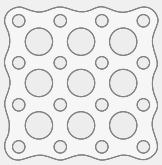
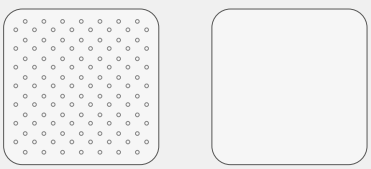
- **green clip:** Ø 1.6 mm
- **red clip:** Ø 2.1 mm

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.

SonicWeld Rx®

SonicPins	Feature and Function	Benefit
	■ Color-coded clip magazines ■ green: SonicPins Ø 1.6 mm ■ red: SonicPins Ø 2.1 mm	■ Easy identification of the appropriate SonicPin diameter
	■ 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 of Resorb x® and Resorb xG product range	■ Complete cross compatibility
	■ 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 designed pin tip for sutures	■ Ideal for endobrow lifting

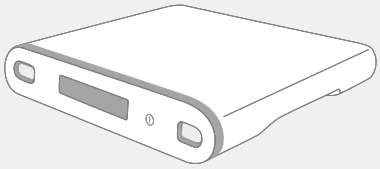
Plates, Meshes, Foils and Membranes		
	■ Huge variety of different geometies, sizes and thicknesses	■ Right implant for every indication
	■ Round edge geometry	■ Minimal palpability and susceptibility
	■ Can easily be contoured in the Xcelsior water bath and cut with scissors intraoperatively	■ Easy adaption to patient-specific anatomy
	■ Flexible meshes	■ Very easy to adapt to patient specific anatomy
	■ Membranes and foils with minimal thickness (0.1, 0.2 or 0.3 mm)	■ Ideal for preprosthetic augmentation
	■ All Resorb x® and Resorb xG implants fit both SonicPin diameters (1.6 and 2.1 mm)	■ Complete cross compatibility
	■ Sterile delivery	■ Always ready to use

Feature, Function and Benefit

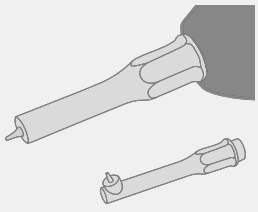
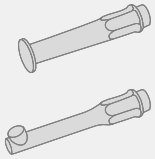
The ultrasonic unit of the SonicWeld Rx® system converts electric energy into mechanical vibrations (ultrasound).

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 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).

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

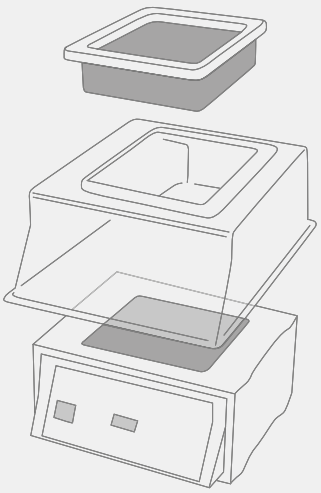
Feature, Function and Benefit

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.

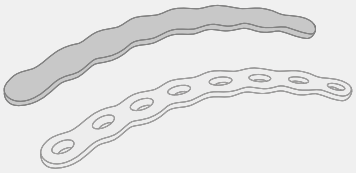
SonicWeld Rx®

Xcelsior water bath



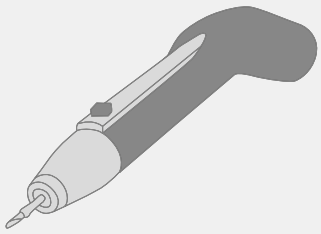
Feature and Function	Benefit
■ Tool for heating up Resorb x® and Resorb xG implants in the hot water (70 - 90 °C / 158 - 194 °F) to adapt it to the patient-specific bone contour	■ Perfect temperature range to adapt Resorb x® and Resorb xG implants
■ Sterilizable material ❶ ❷	■ To be used in the sterile area of the OR

Templates



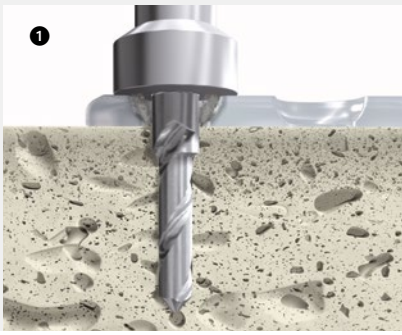
Feature and Function	Benefit
■ Various templates available	■ Template reflects the implant 1-to-1 ■ Safe selection of the sterile-packed implant
■ Adaption of the implant to the patient‘s anatomical condition in the Xcelsior water bath	■ Perfect fit of implant

BOS Drill



Feature and Function	Benefit
■ 600 rev/min, high-speed forward	■ Ideal for predrilling
■ Ergonomic design	■ Safe fit in the user‘s hand
■ Lightweight handle weighing only 200 g	■ Especially indispensable when dealing with a large number of implants
■ Can be operated with a finger	■ Comfortable to use
■ Sterile battery pack simply needs to be clicked-on	■ Always charged and ready for use

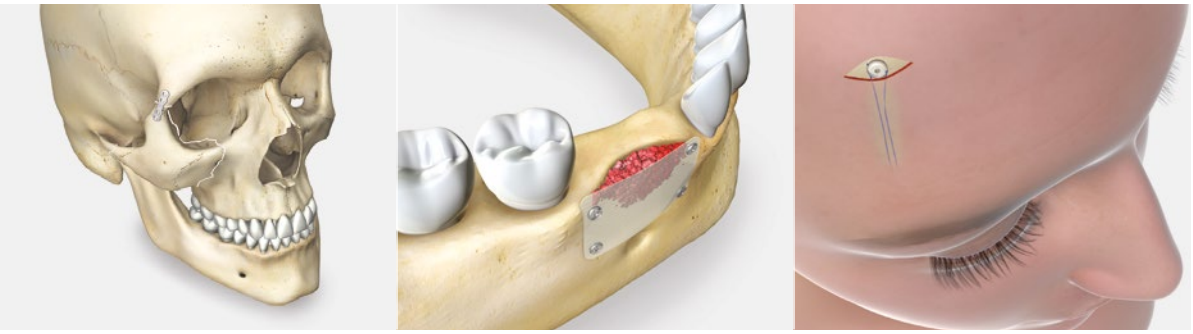
Step by Step
to innovative Osteosynthesis



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

Also see the brochure “SonicWeld Rx® – Surgical Techniques and Product Range”

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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
china@klsmartin.com

KLS Martin India Pvt Ltd.
Chennai · India
Tel. +91 44 66 442 300
india@klsmartin.com

Martin Italia S.r.l.
Milan · Italy
Tel. +39 039 605 67 31
italia@klsmartin.com

Nippon Martin K.K.
Tokyo · Japan
Tel. +81 3 3814 1431
nippon@klsmartin.com

KLS Martin SE Asia Sdn. Bhd.
Penang · Malaysia
Tel. +604 505 7838
malaysia@klsmartin.com

KLS Martin de México S.A. de C.V.
Mexico City · Mexico
mexico@klsmartin.com

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

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

KLS Martin Taiwan Ltd.
Taipei 106 · Taiwan
Tel. +886 2 2325 3169
taiwan@klsmartin.com

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

KLS Martin UK Ltd.
London · United Kingdom
Tel. +44 1189 000 570
uk@klsmartin.com

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

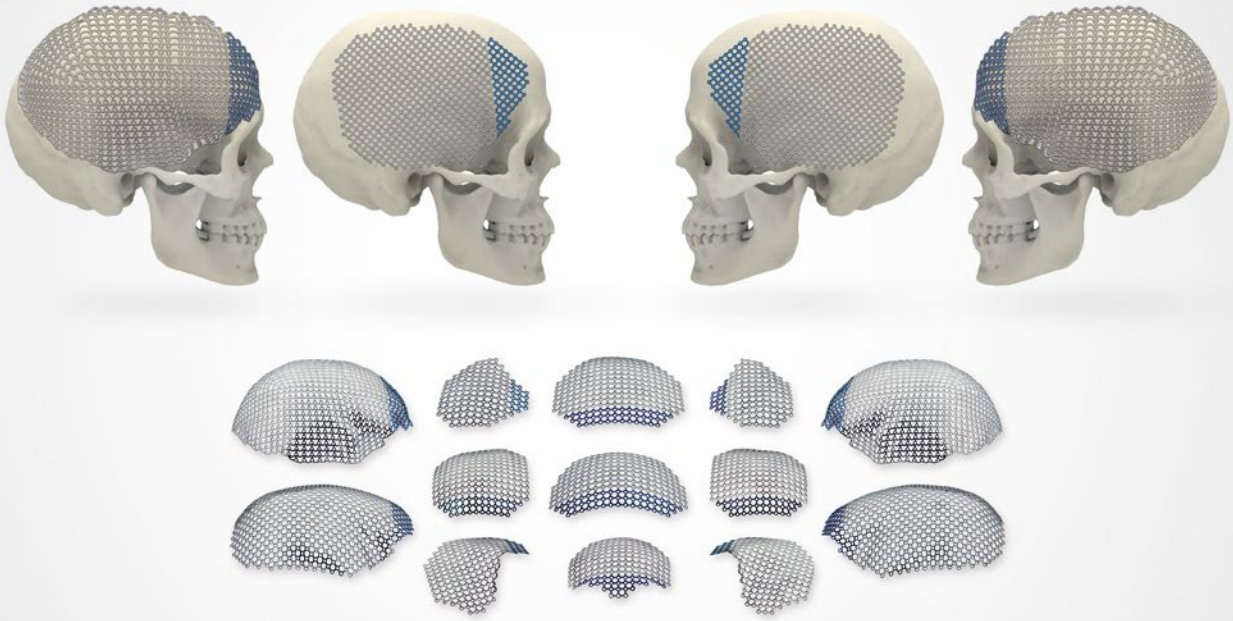
Gebrüder Martin GmbH & Co. KG
A company of the KLS Martin Group
KLS Martin Platz 1 · 78532 Tuttlingen · Germany
P.O. Box 60 · 78501 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com

CE 0297

The KLS Martin SonicWeld Rx® solution is based on the BoneWelding® technology[1] protected by the industrial property rights of WoodWelding AG, Switzerland, and has been licensed by this company.

[1] "BoneWelding"® is a registered Swiss trademark.

KLS martin GROUP



SAM

Standard Approach Mesh
Pre-contoured titanium mesh implants

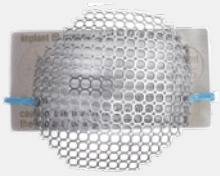
Oral and maxillo-facial surgery is our passion! Its further development, together with our customers, is our ambition. Every day we work on developing innovative products and services which meet the highest demands on quality, and which contribute to the wellbeing of the patient.

SAM – Standard Approach Mesh
Pre-contoured titanium mesh implants

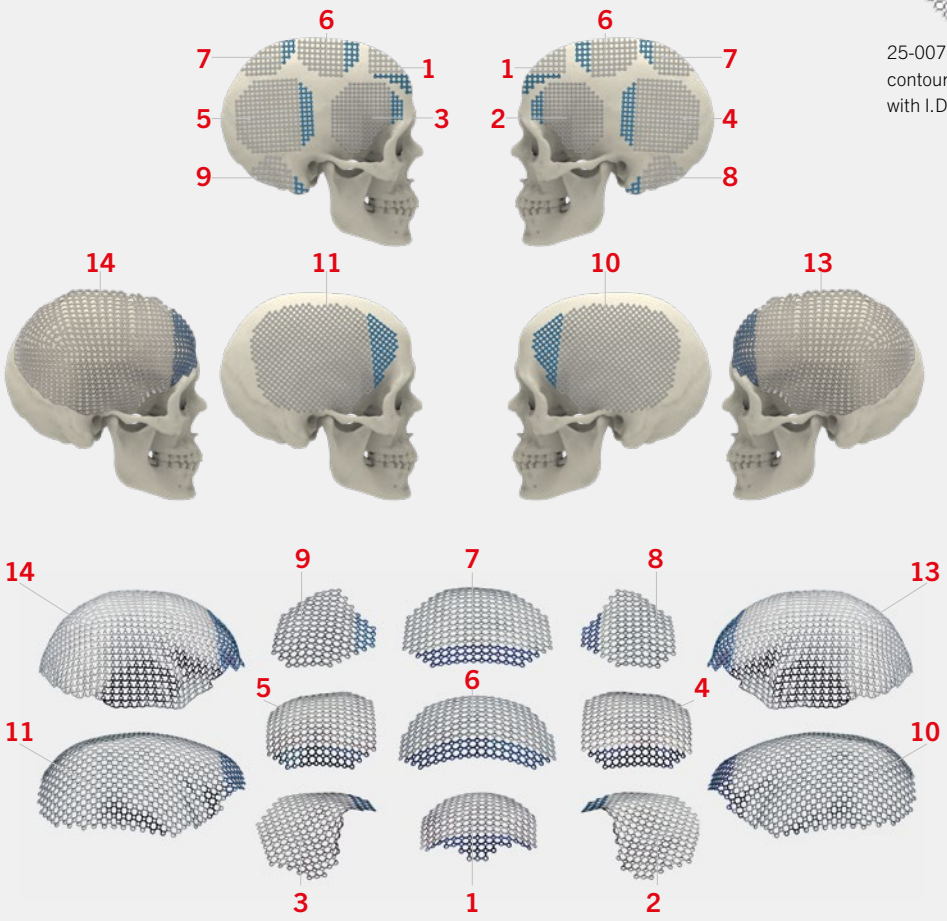
Benefits

- Pre-contoured titanium mesh implants and templates for 11 standard neurosurgical approaches
- Mesh sizes and shapes were created using a compilation of adult CT scans to develop the best possible “average” fit
- 0.6 mm thick titanium: rigid, yet able to modify slightly to match each patient’s specific anatomy
- Used in conjunction with KLS Martin Drill-Free 1.5 mm Neuro maxDrive® screws
- Each implant comes with detachable identification tag to aid in orientation and to maximize inventory control (see below)
- Also available in sterile version

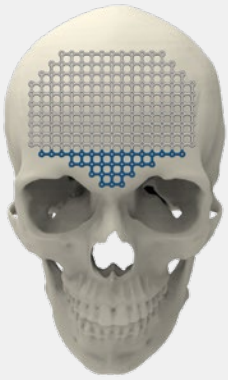
Blue color designates frontal direction of mesh



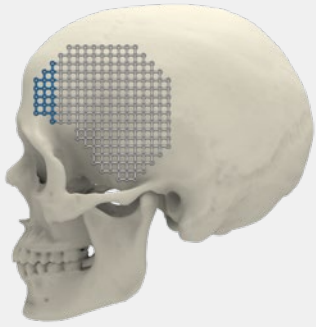
25-007-05-09
contoured mesh
with I.D. tag attached



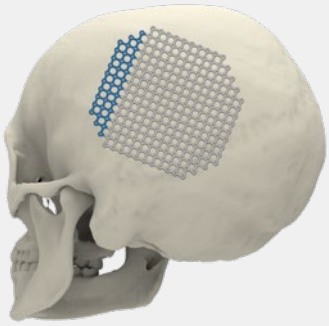
SAM – Standard Approach Mesh
Pre-contoured titanium mesh implants



25-007-01-09 Ti 1
25-007-01-71 Ti 1
Mesh for bifrontal approach
= 0.6 mm

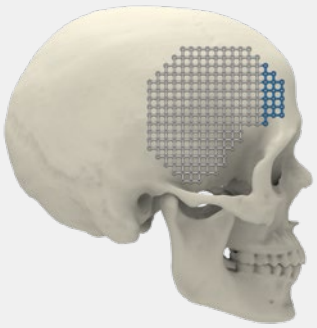


25-007-02-09 Ti 1
25-007-02-71 Ti 1
Mesh for pterional approach, left
= 0.6 mm

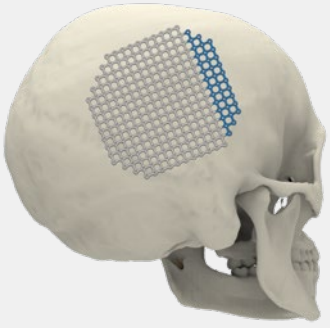


25-007-04-09 Ti 1
25-007-04-71 Ti 1
Mesh for parietal approach, left
= 0.6 mm

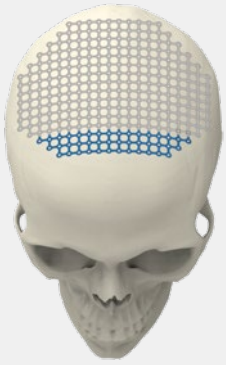
25-007-06-09 Ti 1
25-007-06-71 Ti 1
Mesh for anterior parasagittal approach
= 0.6 mm



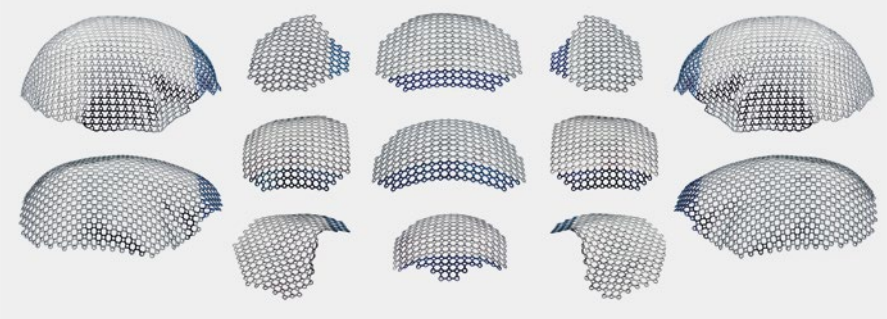
25-007-03-09 Ti 1
25-007-03-71 Ti 1
Mesh for pterional approach, right
= 0.6 mm



25-007-05-09 Ti 1
25-007-05-71 Ti 1
Mesh for parietal approach, right
= 0.6 mm



25-007-07-09 Ti 1
25-007-07-71 Ti 1
Mesh for posterior parasagittal approach
= 0.6 mm



25-007-00-09
Mesh set, pre-contoured, complete
= 0.6 mm

25-007-70-09
Template set

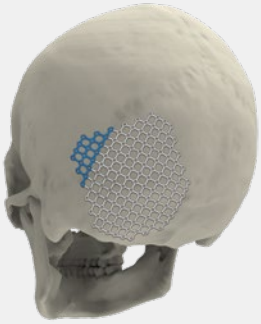
Explanation of icons

Ti Pure titanium

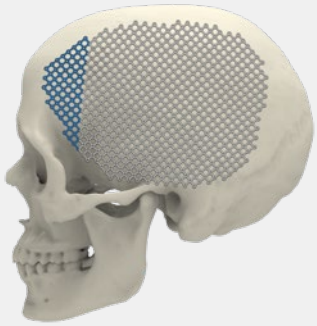
1 Packaging unit

Plate profile

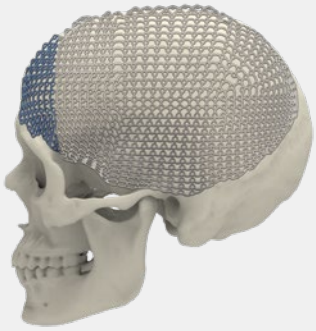
STERILE R Sterile packed implants



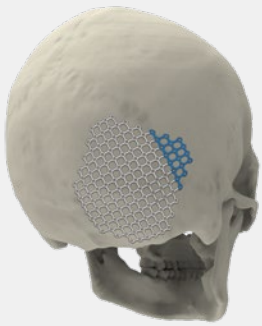
25-007-08-09 Ti 1
25-007-08-71 Ti 1
Mesh for suboccipital approach, left
= 0.6 mm



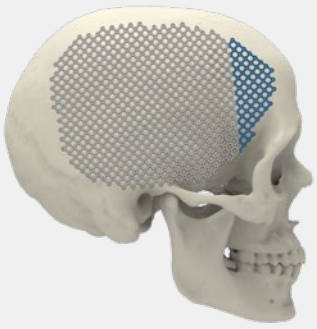
25-007-10-09 Ti 1
25-007-10-71 Ti 1
Mesh for frontotemporoparietal approach, left
= 0.6 mm



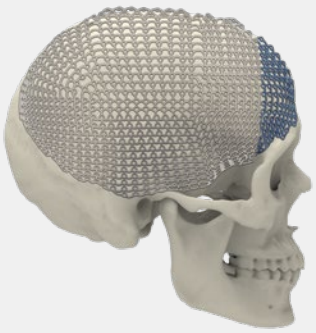
25-007-13-09 Ti 1
25-007-13-71 Ti 1
Mesh for frontotemporoparietal approach, left, XL
= 0.6 mm



25-007-09-09 Ti 1
25-007-09-71 Ti 1
Mesh for suboccipital approach, right
= 0.6 mm



25-007-11-09 Ti 1
25-007-11-71 Ti 1
Mesh for frontotemporoparietal approach, right
= 0.6 mm



25-007-14-09 Ti 1
25-007-14-71 Ti 1
Mesh for frontotemporoparietal approach, right, XL
= 0.6 mm

SAM – Standard Approach Mesh
Pre-contoured titanium mesh implants

55-969-32-04 Mesh tray 30 x 30 cm with lid and silicone mat

Standard Approach Mesh

25-007-00-09	**Mesh set, pre-contured, 0.6 mm complete, consisting of:**	**Qty/unit**
25-007-01-09	Mesh for bifrontal approach	1
25-007-02-09	Mesh for pterional approach, left	1
25-007-03-09	Mesh for pterional approach, right	1
25-007-04-09	Mesh for parietal approach, left	1
25-007-05-09	Mesh for parietal approach, right	1
25-007-06-09	Mesh for anterior parasagittal approach	1
25-007-07-09	Mesh for posterior parasagittal approach	1
25-007-08-09	Mesh for suboccipital approach, left	1
25-007-09-09	Mesh for suboccipital approach, right	1
25-007-10-09	Mesh for frontotemporoparietal approach, left	1
25-007-11-09	Mesh for frontotemporoparietal approach, right	1

All meshes are available in sterile version

55-969-31-04 Mesh tray 30 x 60 cm with lid and silicone mat

Templates

25-007-70-09	Mesh Template Set complete, consisting of:	Qty/unit
25-007-51-09	Mesh Template for bifrontal approach	1
25-007-52-09	Mesh Template for pterional approach, left	1
25-007-53-09	Mesh Template for pterional approach, right	1
25-007-54-09	Mesh Template for parietal approach, left	1
25-007-55-09	Mesh Template for parietal approach, right	1
25-007-56-09	Mesh Template for anterior parasagittal approach	1
25-007-57-09	Mesh Template for posterior parasagittal approach	1
25-007-58-09	Mesh Template for suboccipital approach, left	1
25-007-59-09	Mesh Template for suboccipital approach, right	1
25-007-60-09	Mesh Template for frontotemporoparietal approach, left	1
25-007-61-09	Mesh Template for frontotemporoparietal approach, right	1

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
china@klsmartin.com

KLS Martin India Pvt Ltd.
Chennai · India
Tel. +91 44 66 442 300
india@klsmartin.com

Martin Italia S.r.l.
Milan · Italy
Tel. +39 039 605 67 31
italia@klsmartin.com

Nippon Martin K.K.
Tokyo · Japan
Tel. +81 3 3814 1431
nippon@klsmartin.com

KLS Martin SE Asia Sdn. Bhd.
Penang · Malaysia
Tel. +604 505 7838
malaysia@klsmartin.com

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

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

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

KLS Martin UK Ltd.
London · United Kingdom
Tel. +44 1189 000 570
uk@klsmartin.com

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

Gebrüder Martin GmbH & Co. KG
A company of the KLS Martin Group
KLS Martin Platz 1 · 78532 Tuttlingen · Germany
P.O. Box 60 · 78501 Tuttlingen · Germany
Tel. +49 7461 706-0 · Fax +49 7461 706-193
info@klsmartin.com · www.klsmartin.com