

SonicWeld *Rx*TM



A NEW ERA IN RESORBABLE
CRANIOFACIAL OSTEOSYNTHESIS

KLS martin L.P.

SonicWeld Rx™ – the osteosynthesis revolution

Conventional osteosynthesis techniques used in craniofacial surgery still represent a compromise, hampered by inherent limitations that often make them time-consuming and costly. With SonicWeld Rx™, the KLS Martin Group has developed the perfect solution, a revolutionary system for craniofacial resorbable fixation that is stable, fast and effortless.

The start of a new era

SonicWeld Rx™ opens up totally new horizons. The ultrasonic technique, coupled with resorbable materials, makes the surgeon's and patient's lives distinctly easier. Thanks to the completely novel, ultrasound-controlled welding process, the resorbable material penetrates deep into the bone structures, leading to a three-dimensional anchorage that gives the surgeon fast and unrivaled stability with little effort. Since the entire implant is resorbable, no second operation is required – an important advantage especially for osteosyntheses performed on the growing skulls of children. Additionally, SonicWeld Rx™ can be used for indications beyond the reach of conventional osteosynthesis – conveniently, quickly and safely.



The SonicWelder Rx with sonotrode is part of the SonicWelder Rx™ system. It is used to weld the specially designed pins directly into the bone structures by ultrasound.

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Complete & flexible

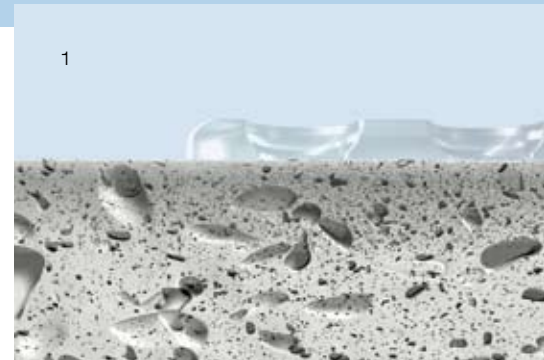
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The SonicWeld Rx™ principle

With SonicWeld Rx™, craniofacial osteosynthesis becomes a much easier application. A completely resorbable SonicPin Rx is inserted into a predrilled hole by ultrasound. It merges with the plate and penetrates into all bone cavities. As a result, implant insertion takes far less time than is required for screw-based osteosynthesis procedures.

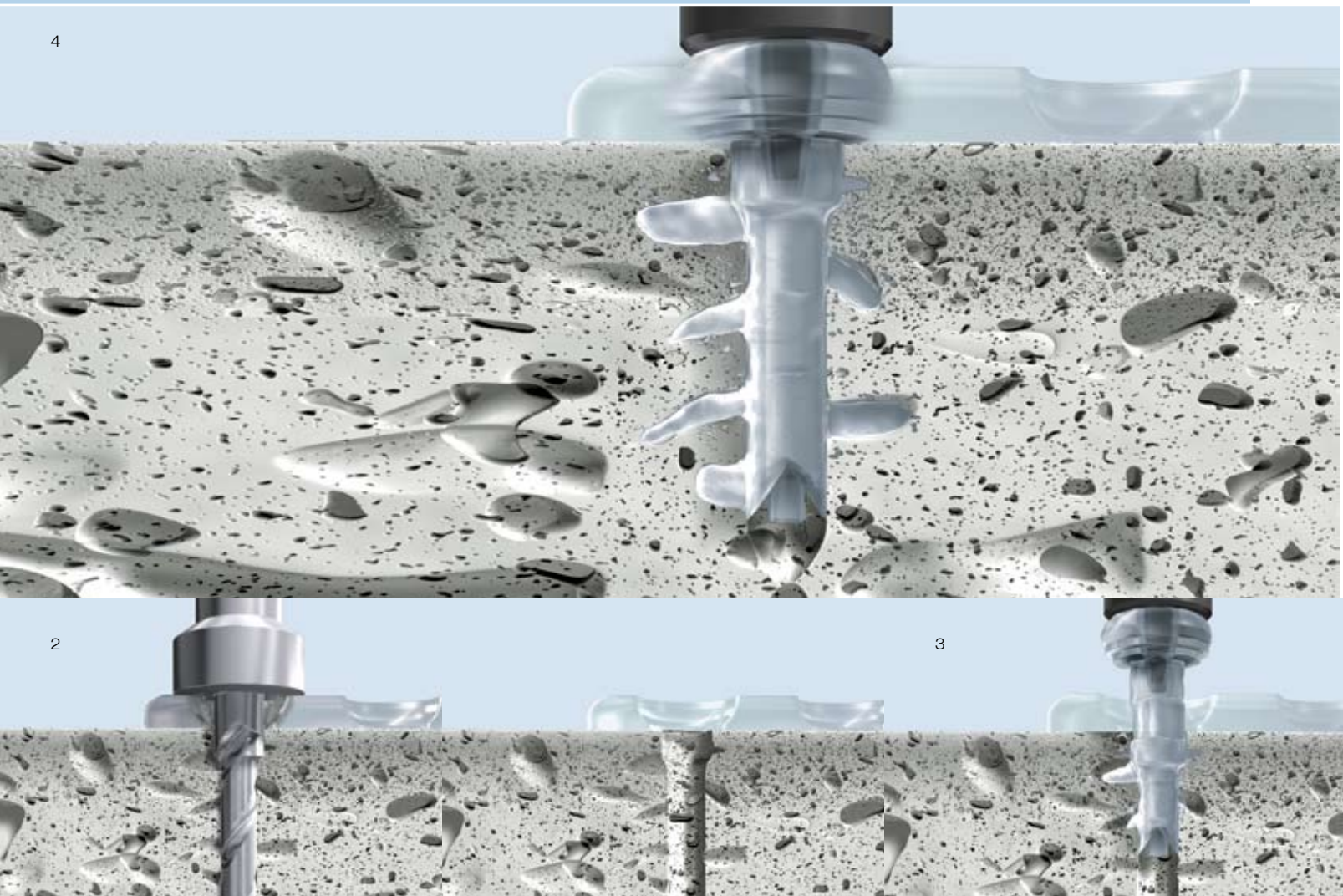


The new form of resorption

The welding of the SonicPins Rx not only increases stability, but allows you to use the system for cancellous bone structures. This novel technology requires no follow-up operation because the implants are completely degradable. Moreover, the system's flexibility, stability and resorbability make it ideal for pediatric surgery.

The advantages

- **Stable:** The bond between the SonicPins Rx and the plate increases mechanical stability. And as the SonicPins Rx fill all cavities of the bone structure, SonicPins Rx ensure the highest three-dimensional stability in a resorbable implant. Additionally, screw breakage is now a thing of the past!
- **Versatile:** The SonicPins Rx take excellent hold in any bone structure, whether cortical or cancellous.
- **Flexible:** It is possible to insert the SonicPins Rx at an angle, allowing the system to be easily used even under difficult anatomical conditions.

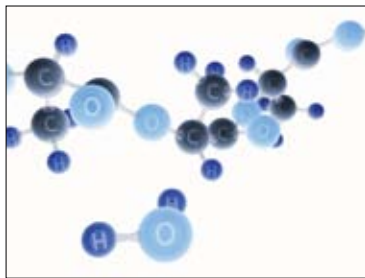


Osteosynthesis with SonicWeld Rx™ - a very simple procedure: Adapt the plate/mesh (1), predrill the hole (2), insert the SonicPin Rx; the sonotrode's ultrasonic vibrations cause the SonicPin Rx to melt and flow into the predrilled hole (3). In this process, the SonicPin Rx combines with the plate/mesh and penetrates into all cavities of the bone structure (4).

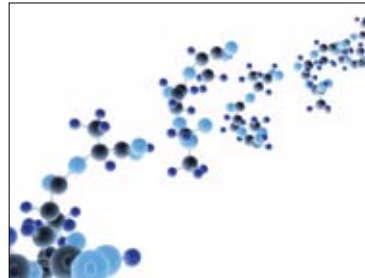
- **Fast:** Easy handling shortens operating times.
- **Cost-efficient:** A single intervention, no follow-up operation requiring anesthesia – which means considerably lower costs and fewer risks. Compact basic instrument set.

The material

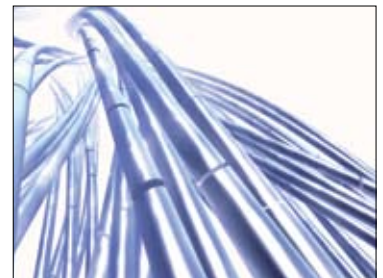
SonicWeld Rx™ is based on our Resorb-X® PDLLA implants. PDLLA consists of lactides and is 100% amorphous. The biological degradation process by hydrolysis is predictable and produces no crystalline tissue changes. All constituents are completely discharged through the metabolic channels with no residues left.



2



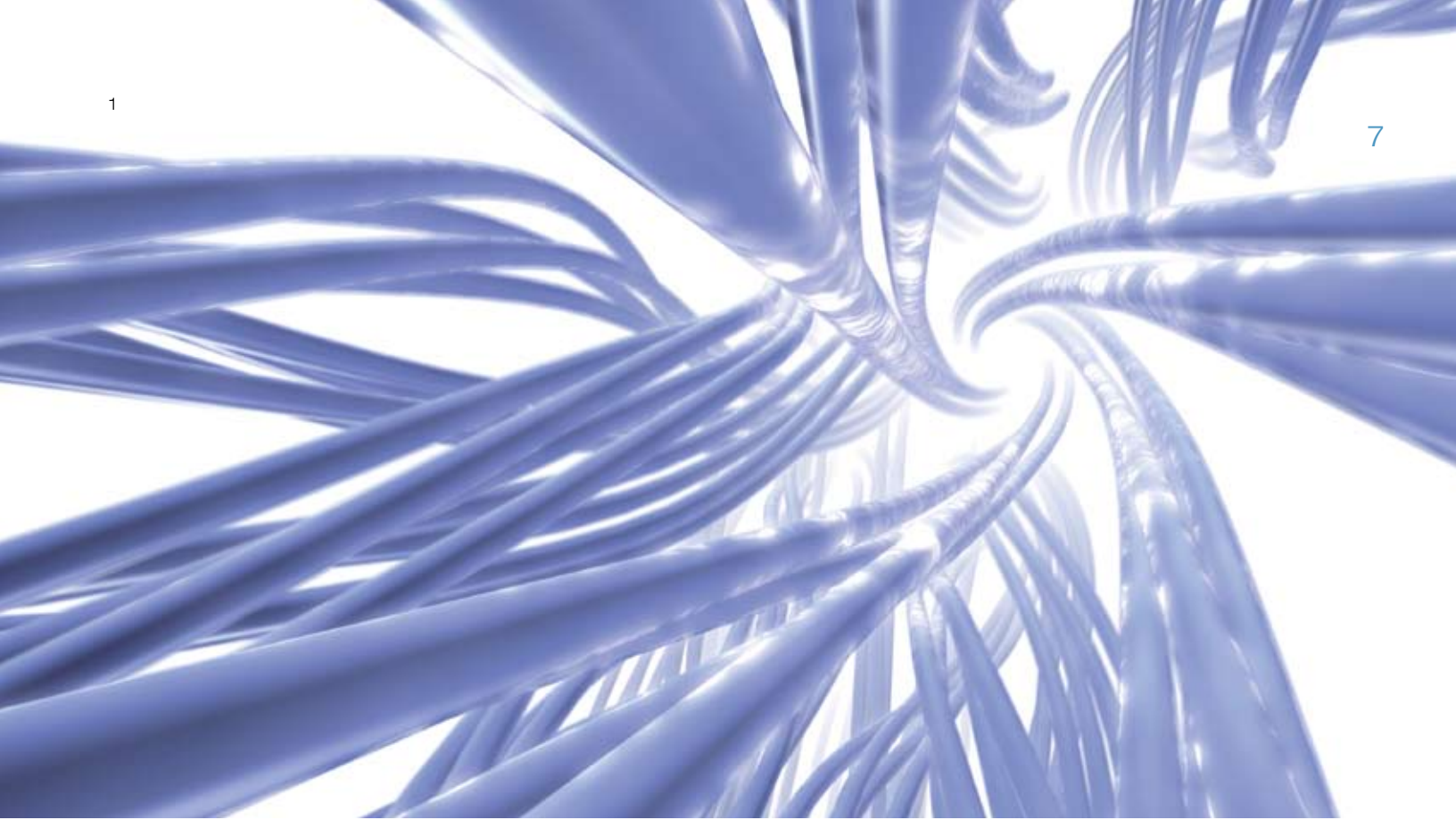
3



4

The advantages

- **Controlled:** PDLLA is the only completely amorphous material consisting of D-lactide and L-lactide (each 50%). As both components are present in the same proportion, the biological degradation process is both predictable and safe.
- **Compatible:** The implants are tissue-friendly. No symptoms such as irritations, inflammations or foreign-body reactions have ever been observed.
- **Natural:** Implant degradation takes place through hydrolysis. All constituents of the material are completely discharged by metabolic processes with no residues left.
- **Validated:** In conjunction with PDLLA, SonicWeld Rx™ offers you a clinically certified, validated and patented total system that has been thoroughly tested in large-scale test series.
- **Flexible:** Even large meshes can be easily and flexibly adapted to the bone surface after heating them in the Xcelsior water bath. Once cooled, the material turns rigid again and reliably retains its shape.



The core of the innovation: a step into the future

The PDLLA material's complex polymer chains (1) absorb the water contents (H_2O molecules) of surrounding body fluids (2) – a process called “hydrolysis”. The stored water then initiates the degradation process, continuously breaking down the long polymer chains into ever shorter structures or simpler molecules (3, 4). The human metabolism subsequently transforms the D-lactides and L-lactides into carbon dioxide and water. Both these compounds are discharged naturally. This degradation process is predictable and complete with no residues left.

The degradation process

- **Supporting:** The material's defined mechanical strength at implantation time is retained for eight to ten weeks, allowing complete fracture healing and bone regeneration.
- **Regenerative:** The material degrades at the same speed as ossification takes place.
- **Complete:** Complete degradation of the SonicPins Rx and full drill-hole ossification. No residues left, no crystalline tissue changes.

Clinical results

Biological basic research, comprehensive mechanical and histological test series and clinical validation give you the confidence and peace of mind you need as a user: SonicWeld Rx™ has an excellent initial strength, is perfectly body-compatible and characterized by a calculable and safe biological degradation process.



Longitudinal section through SonicPin Rx and supporting tissue immediately after the operation

Histological findings

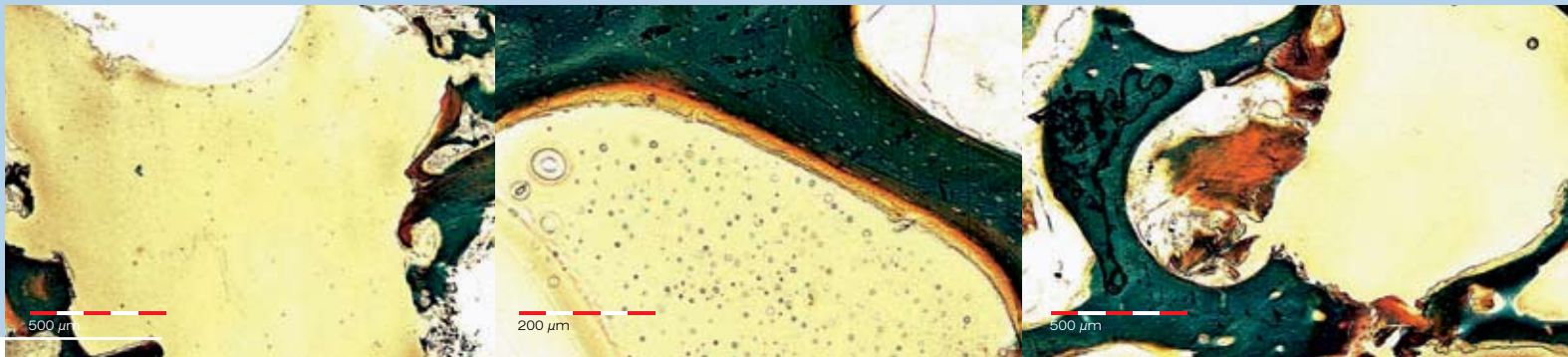
- No thermal tissue damage or even necroses have ever been observed.
- Total absence of any clinical or histological indication for an initial inflammatory response caused in the surrounding tissue by ultrasound application.
- There are no bone-damaging secondary responses.
- The soft-tissue response classifies as “non-irritating” clinically as well as histologically.

Mechanical findings

- The mechanical strength of SonicPins Rx is significantly higher than that of conventional plate-and-screw osteosyntheses.
- What’s particularly impressive is the increased primary strength of the SonicPins Rx, due to direct polymer anchorage in the trabecular meshwork of the bone.

Histological images: University Carl Gustav Carus of the Technical University of Dresden, Hospital for Oral and Maxillofacial Surgery, Dr. Dr. Ronald Mai and Prof. Dr. Dr. Uwe Eckelt (director)

Clinical results: University Carl Gustav Carus of the Technical University of Dresden, Hospital for Prosthetic Dentistry, headed by Prof. Dr. Bernd Reitemeier



32 days after pin insertion

3 months after the operation

Another image also taken 3 months after the operation

Important questions & answers

Does SonicPin Rx phase change heat up the tissue around the pin?

Temperature increase is minimal and disappears within seconds. Therefore, no pain or even necroses have been seen.

Does the treatment cause traumatization?

No. Clinical experience supports the following statements:

- No bone destruction or degradation as a result of thermal damage
- Intact bone structures at the pin implantation site
- No difference concerning the dynamics and quality of bone regeneration, compared with traditional screw fixation
- No signs of inflammation
- No scars or tissue adhesions

Does this surgical technique cause pain?

No signs of pain could be observed. Insertion of a SonicPin Rx causes less traumatization than predrilling the hole.

Indications

- Neurosurgery
- Syndrome patients (e.g. Apert's, Crouzon's)
- Pediatric and craniofacial surgery

Contraindications

- High-load regions (such as the mandible)
- Acute or latent infections
- Patients in poor health or suffering from metabolic disorders (e.g. diabetes)

The program with a system

SonicWeld Rx™ is a flexible system, fully compatible with KLS-Martin's Resorb-X® range of plates and meshes, so all SonicPins Rx can be freely combined with any resorbable plate or mesh product from KLS-Martin.



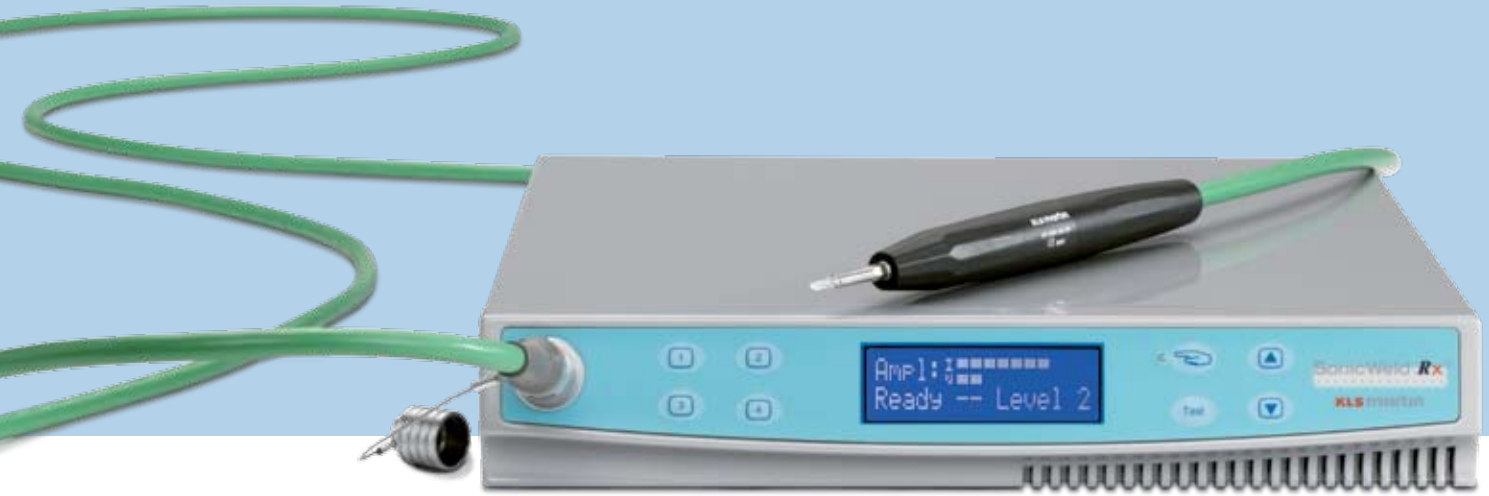
Plates, meshes and pins can be conveniently stored

Plates and meshes

- All plates have the same thickness of 1.0 mm.
- The meshes are available in thicknesses of 0.3 mm, 0.6 mm and 1.0 mm.
- A multitude of different mesh designs gives users maximum flexibility for optimum patient treatment.
- The special "rounded edge" geometry additionally supports a body-compatible degradation process.

SonicPins Rx

- The SonicPins Rx are available in diameters of 1.6 mm and 2.1 mm.
- The SonicPins Rx are self-retaining so they can be safely and conveniently picked up with the tip of the sonotrode.
- The optimized shape of the SonicPins Rx guarantees easy insertion plus a strong hold in the bone.



SonicWelder Rx and sonotrode are the heart of SonicWeld Rx™

Sonotrodes

- Maximum safety and operator convenience due to the self-retaining SonicPins Rx and a handle that illuminates the surgical site.
- Completely sterilizable (134°C / 273°F).
- Easy replacement.

SonicWelder Rx

- The SonicWeld Rx™ technology utilizes the principle of ultrasonic frequency. The micro-vibrations generated by a defined ultrasonic frequency cause the pin's outer surface to melt as it comes in contact with a hard surface like bone. As a result, the SonicPin Rx simply flows into the predrilled hole.

The system components


Different requirements, different materials. Always right: SonicWeld Rx™ and its comprehensive range of accessories. Optimally adapted for use in the OR – and optimally integrated into a total system as well.



SonicPins Rx





Twist Drills (for predrilling)

SonicPins Rx		
	Dimensions (mm)	Item Number
	1.6 x 4	52-516-54
	1.6 x 5	52-516-55
	1.6 x 6	52-516-56
	1.6 x 7	52-516-57
	2.1 x 4	52-521-54
	2.1 x 5	52-521-55
	2.1 x 7	52-521-57
	2.1 x 9	52-521-59

SonicWeld Rx™		
Designation/ Unit	Quantity	Item Number
SonicWelder Rx complete	1 unit	52-500-00
consisting of:		
Ultrasound device	1 unit	52-500-01
Footswitch with cable	1 unit	52-500-02
Handpiece with cable	1 unit	52-500-03
Sonotrode tip, straight	1 unit	52-501-01
Tip wrench*	1 unit	52-502-01
Case	1 unit	52-502-02

* for sonotrode

Twist Drills			
Stryker attachment	Dimensions (mm)	Item Number	
	for 1.6 mm SonicPins Rx	1.0 x 50 x 5	52-510-05
		1.0 x 50 x 6	52-510-06
		1.0 x 50 x 7	52-510-07
		1.0 x 50 x 8	52-510-08
for 2.1 mm SonicPins Rx	1.6 x 50 x 5	52-516-05	
	1.6 x 50 x 6	52-516-06	
	1.6 x 50 x 8	52-516-08	
for BOS Drill	1.6 x 50 x 10	52-516-10	
		Dimensions (mm)	Item Number
		for 1.6 mm SonicPins Rx	1.0 x 40 x 5
	1.0 x 40 x 8	52-610-08	
for 2.1 mm SonicPins Rx	1.6 x 40 x 5	52-616-05	
	1.6 x 40 x 10	52-616-10	



Storage and processing tray



Xcelsior water bath



BOS Drill



Xcelsior water bath

Category	Scope	Item Number
Water bath	complete	52-400-10
consisting of:		
Heating unit	separate	52-400-11
Water container	separate	52-400-12
Cover	separate	52-400-13

Our BOS Drill neatly rounds off the SonicWeld Rx™ system. This battery-operated drill gives you the necessary flexibility as it works independently from clinical motor systems. It can be disinfected and steam-sterilized (at 134°C / 273°F).

Thanks to the perfect combination of ergonomics and design, high-quality materials and advanced manufacturing technologies, this product has received the IF Design Award 2005.

Storage and processing tray

Category	Scope	Item Number
Instrument tray, 30 cm x 30 cm, with lid	complete	55-969-38
consisting of:		
Instrument tray, 30 cm x 30 cm*	separate	55-969-28
Lid for storage tray	separate	55-963-38
* without lid		

BOS Drill

Category	Item Number
BOS Drill w/o battery pack	50-800-03
Battery pack (10 units)	50-800-02

The system components

Different requirements, different dimensions. Always right: SonicWeld Rx™ and its comprehensive range of accessories. Optimally adapted for use in the OR – and optimally integrated into a total system as well. All plates are depicted at a 1:1 scale, all meshes at a 1:2 scale.



STERILE R

Al Aluminium

1:1 scale

a)



b)



Item no.

52-075-04 **1**

52-077-04 **1**

52-076-04 **1**

a)

Resorb-X® mini plate,
4 hole, regular

Resorb-X® mini plate,
4 hole, medium

Resorb-X® mini plate,
4 hole, long

Item no.

52-175-04 **1 Al**

52-177-04 **1 Al**

52-176-04 **1 Al**

b)

Resorb-X® template,
4 hole, regular

Resorb-X® template,
4 hole, medium

Resorb-X® template,
4 hole, long

t =

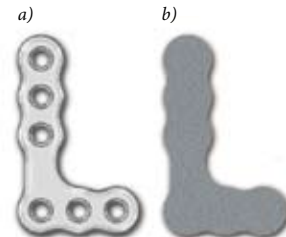
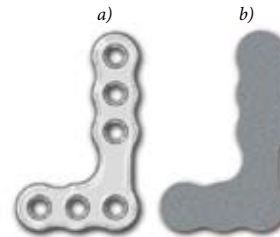
1.0 mm

1.0 mm

1.0 mm

1:1 scale

a)



b)



Item no.

52-075-08 **1**

52-095-06 **1**

52-096-06 **1**

a)

Resorb-X® mini plate,
straight, 8-hole, regular

Resorb-X® mini plate,
L-shape, left, regular, 3 x 3

Resorb-X® mini plate,
L-shape, right, regular, 3 x 3

Item no.

52-175-08 **1 Al**

52-196-06 **1 Al**

52-196-06 **1 Al**

b)

Resorb-X® template,
8-hole, regular

Resorb-X® template,
L-shape, regular

Resorb-X® template,
L-shape, regular

t =

1.0 mm

1.0 mm

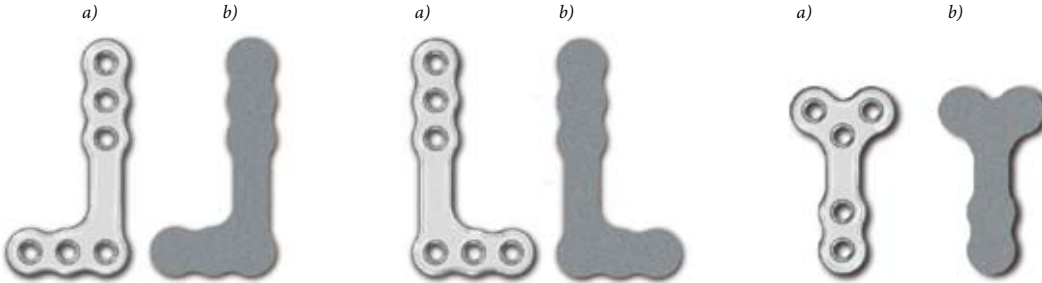
1.0 mm

1:1 scale



Item no. 52-076-22
 Resorb-X® mini plate,
 straight, 22-hole
 t = 1.0 mm

1:1 scale



Item no. 52-095-07
 a) Resorb-X® mini plate,
 L-shape, left, long, 3 x 3

Item no. 52-096-07
 Resorb-X® mini plate,
 L-shape, right, long, 3 x 3

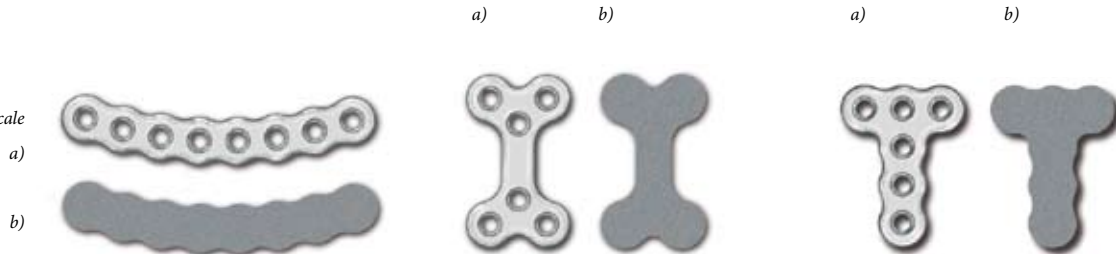
Item no. 52-085-05
 Resorb-X® mini plate,
 Y-shape, 5-hole

Item no. 52-196-07
 b) Resorb-X® template,
 L-shape, long
 t = 1.0 mm

Item no. 52-196-07
 Resorb-X® template,
 L-shape, long
 1.0 mm

Item no. 52-185-05
 Resorb-X® template,
 Y-shape
 1.0 mm

1:1 scale



Item no. 52-076-08
 a) Resorb-X® mini plate,
 orbital, 8-hole

Item no. 52-090-06
 Resorb-X® mini plate,
 double Y-shape, 6-hole

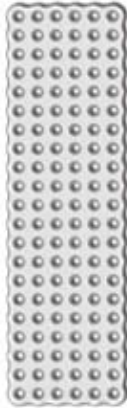
Item no. 52-088-06
 Resorb-X® mini plate,
 T-shape, 6-hole


Item no. 52-176-08
 b) Resorb-X® template,
 orbital, 8-hole
 t = 1.0 mm

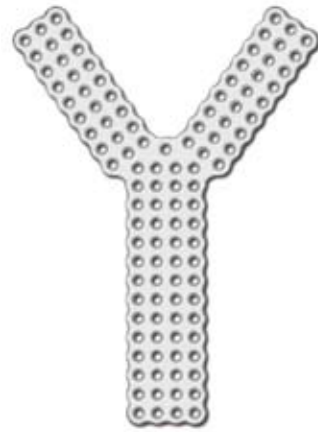
Item no. 52-190-06
 Resorb-X® template,
 double Y-shape
 1.0 mm


Item no. 52-188-06
 Resorb-X® template,
 T-shape
 1.0 mm

1:2 scale




Item no. **52-310-31** 
 Resorb-X® mesh panel,
 small grid, 31 x 106 mm
 t = 1.0 mm

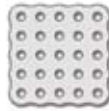



52-310-30 
 Resorb-X® mini plate,
 Y-shape, Wood-style
 1.0 mm

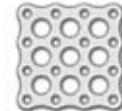
1:2 scale




Item no. **52-310-25** 
 Resorb-X® mesh panel,
 small grid, 25 x 25 mm
 t = 1.0 mm




52-303-25 
 Resorb-X® mesh panel,
 small grid, 25 x 25 mm
 0.3 mm

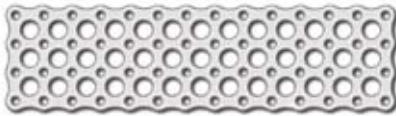



52-303-26 
 Resorb-X® mesh panel,
 large grid, 25 x 25 mm
 0.3 mm

Item no.


52-306-25 
 Resorb-X® mesh panel,
 small grid, 25 x 25 mm
 t = 0.6 mm

1:2 scale



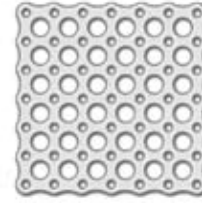
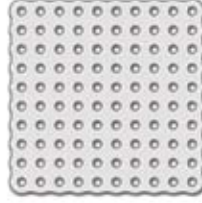
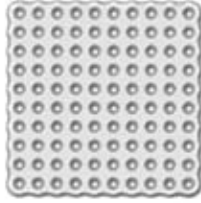
Item no. **52-306-27** 
 Resorb-X® mesh panel,
 large grid, 25 x 100 mm
 t = 0.6 mm





52-310-11 
 Resorb-X® mesh strip,
 2-hole, small grid, 11 x 126 mm
 1.0 mm


Item no. **52-310-27** 
 Resorb-X® mesh panel,
 large grid, 29 x 104 mm
 t = 1.0 mm

1:2 scale





Item no. 52-310-50 
 Resorb-X® mesh panel,
 small grid, 50 x 50 mm
 t = 1.0 mm

Item no. 52-303-50 
 Resorb-X® mesh panel,
 small grid, 50 x 50 mm
 0.3 mm

Item no. 52-303-51 
 Resorb-X® mesh panel,
 large grid, 50 x 50 mm
 0.3 mm


Item no.

52-306-50 
 Resorb-X® mesh panel,
 small grid, 50 x 50 mm
 0.6 mm

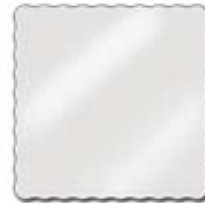
52-306-51 
 Resorb-X® mesh panel,
 large grid, 50 x 50 mm
 0.6 mm


Item no.


t =


52-310-53 
 Resorb-X® mesh panel,
 large grid, 50 x 50 mm
 1.0 mm

1:2 scale




Item no. 52-306-40 
 Resorb-X® mesh panel,
 orbital floor, 40 x 40 mm
 t = 0.6 mm

Item no. 52-310-55 
 Resorb-X® mesh panel,
 round, 55 mm diameter

Item no. 52-303-52 
 Resorb-X® foil panel,
 solid, 50 x 50 mm
 0.3 mm


Item no.

t =

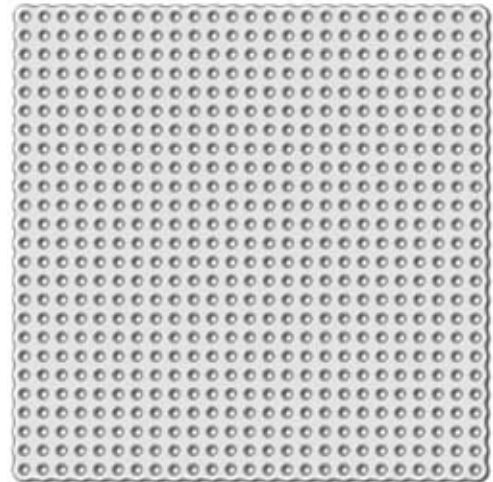
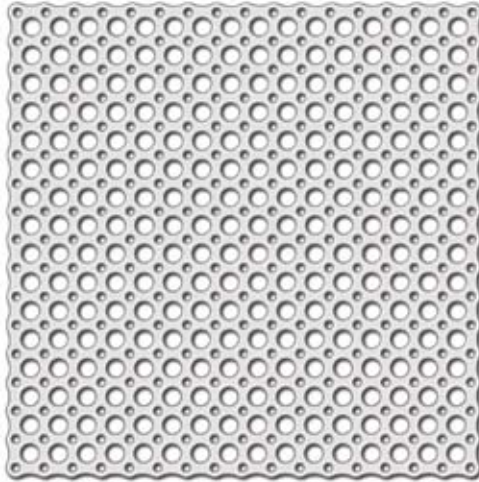
52-306-52 
 Resorb-X® foil panel,
 solid, 50 x 50 mm
 0.6 mm


Item no.


t =


52-310-52 
 Resorb-X® foil panel,
 solid, 50 x 50 mm
 1.0 mm

scale 1:2



Item no. 52-306-12 
Resorb-X® mesh panel,
large grid, 125 x 125 mm
t = 0.6 mm

52-310-13 
Resorb-X® mesh panel,
small grid, 126 x 126 mm
1.0 mm

Item no. 52-310-12 
Resorb-X® mesh panel,
large grid, 125 x 125 mm
t = 1.0 mm

If you have any questions...

...we will be glad to answer them anytime with additional information in the form of product brochures and a CD-ROM that vividly describe and illustrate the SonicWeld Rx™ principle.

Of course, you can also reach us personally, either by e-mail or through our customer hotline.

Additional product brochures and information materials

- Resorb-X® Brochure
- SonicWeld Rx™ CD-ROM
- Level One Catalog
- BOS Driver & Drill

Customer hotline: 800.625.1557

E-mail: sonicweld-rx@klsmartin.com



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

¹⁾"BoneWelding" is a registered Swiss trademark

