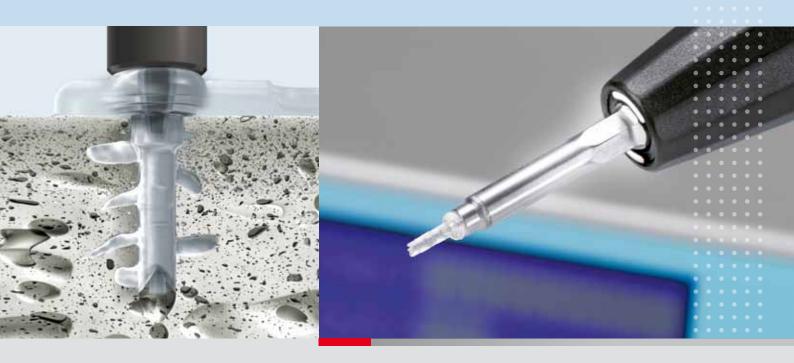
# Osteosynthesis



# SonicWeld Rx®

A new era in craniofacial osteosynthesis



# SonicWeld Rx<sup>®</sup> – the osteosynthesis revolution

Conventional osteosynthesis techniques used in oral and maxillofacial surgery and neurosurgery still represent a compromise, hampered by inherent limitations that often make them time-consuming and costly too. With SonicWeld Rx\*, the KLS Martin Group has developed the perfect solution, a revolutionary system for craniofacial fixation that is stable and resorbable, fast and effortless. Ideally suitable in cortical and in cancellous bone.

## The start into a new era

SonicWeld Rx<sup>®</sup> opens up totally new horizons in osteosynthesis. The advanced ultrasonic technique, coupled with resorbable materials, makes the surgeon's and patient's lives distinctly easier. Thanks to the completely novel, ultrasound-based welding process, the resorbable material penetrates deeply into the bone structures, taking firm hold there to generate a three-dimensional primary stability previously unknown. And because all implant components are resorbable, no second operation is required – an important advantage especially for osteosyntheses performed on the growing skulls of children.

SonicWeld  $Rx^{\circ}$  – a system that combines primary stability with convenience, speed, ease of use and safety.



The SonicWelder Rx with sonotrode is part of the larger SonicWeld  $Rx^{\circ}$  system. It is used to weld specially designed SonicPins Rx directly into the bone structures.

## Contents:

Fast & safe The SonicWeld Rx® principle	Page 4
<b>Amorphous &amp; pure</b> The material	Page 6
Questions & answers Clinical results	Page 8
Validated & compatible The program with a system	Page 10
<b>Complete &amp; flexible</b> The system's components	Page 14
Info & more Product brochures and CD-ROM	Page 23

# The SonicWeld Rx® principle

With SonicWeld Rx\*, craniofacial osteosynthesis becomes a much easier intervention. 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 only half the time usually required for screw-based osteosynthesis procedures using resorbable materials.



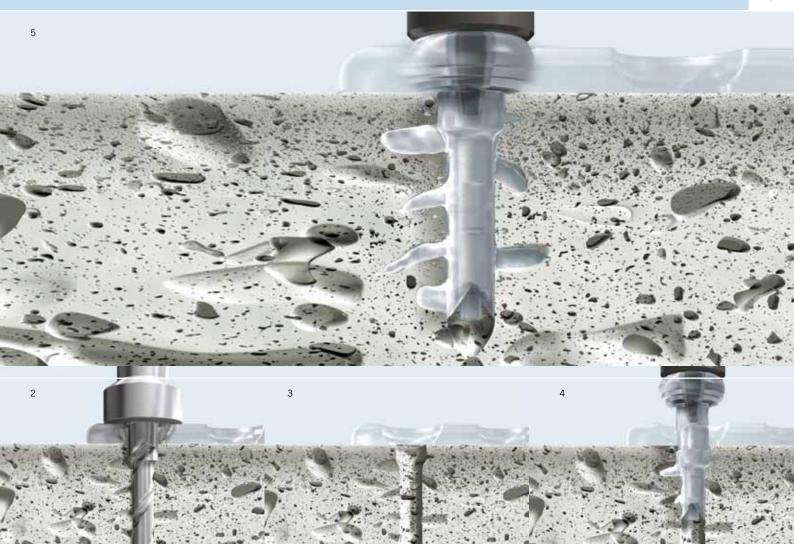
### The new form of resorption

The welding-in process gives the SonicPins Rx primary stability to a degree previously unknown in resorbable implants. As a result, the three-dimensional reconstruction is significantly more rigid, especially where major, large-surface interventions are concerned.

Besides, SonicWeld Rx<sup>®</sup> permits firm anchorage of resorbable implants in spongy bone structures as well. Never before has such an application been possible in OMF surgery! This novel technology also spares you a follow-up operation because the implant material is completely degradable. Moreover, the system's flexibility, stability and resorbability make it ideal for pediatric trauma interventions. Validated and clinically tested.

### The advantages

- **Stable:** The bond between the pins and the plate increases mechanical stability. As the SonicPins Rx fill all cavities of the bone structure, SonicWeld Rx<sup>®</sup> ensures highest three-dimensional stability. Besides, screw breakage is now definitely a thing of the past because the SonicPins Rx are inserted axially straight!
- **Versatile:** The SonicPins Rx take excellent hold in any bone structure, whether cortical or spongy. Even tiny fragments can be fixed in place securely and rotation-proof, due to the absence of conventional screw-in resistances.
- **Flexible:** The SonicPin Rx can be flexibly used even in cramped quarters and under difficult anatomical conditions. For example, it can be implanted at an angle.

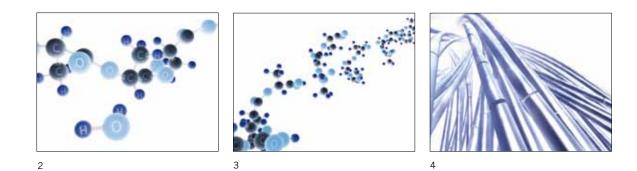


Osteosynthesis with SonicWeld  $Rx^{\circ}$  – a very simple procedure: Adapt the plate/mesh (1), predrill the hole (2) and insert the SonicPin Rx (3). The sonotrode's ultrasonic vibrations cause the SonicPin Rx to melt on the surface and glide into the predrilled hole (4). In this process, the SonicPin Rx combines with the plate/mesh and penetrates into all bone cavities (5).

- **Fast:** Easy handling shortens operating times significantly. Compared with conventional resorbable screws, treatment time can be cut to half.
- Cost-efficient: Advanced resorbable technology means a single intervention for you – i.e. no follow-up operation with its associated risks and costs (anesthesia, infection risk, hospitalization, loss of earnings).
  The compact basic instrument set minimizes the initial investment and makes the system manageable.

# The material

SonicWeld Rx<sup>\*</sup> is based on our Resorb-x<sup>\*</sup> product range, consisting of the same base material: **P**oly-**D** and **L**-**L**actic **A**cid (PDLLA), which is 100% amorphous. The biological degradation process by hydrolysis is predictable. There are no crystalline residues, no tissue irritations. All constituents are completely discharged through the metabolic channels.



#### 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 to the highest possible degree. No symptoms such as irritation, inflammation 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 – no residues left.

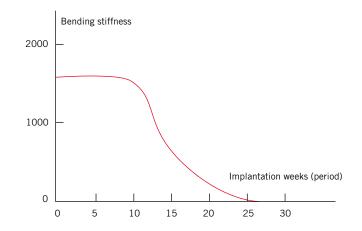
- Validated: In conjunction with PDLLA, SonicWeld Rx<sup>®</sup> offers you a clinically certified, validated and patented total system that has been thoroughly tested in large-scale test series.
- Flexible: Even large meshes can be easily and flexibly adapted to the bone surface after heating them in the Xcelsior water bath. Once cooled down, the material turns rigid again and reliably retains its shape.



### The degradation process - reliable yet invisible

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 molecular chains (3, 4). The human metabolism subsequently transforms the D-lactides and L-lactides into carbon dioxide and water. Both these compounds are finally discharged naturally. This degradation process is predictable and complete – no residues are left.

- **Strong:** 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 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 resorbable plate-and-screw osteosyntheses.
- What's particularly impressive is the increased primary stability of the SonicPins Rx, due to direct polymer anchorage in the trabecular meshwork of the bone.

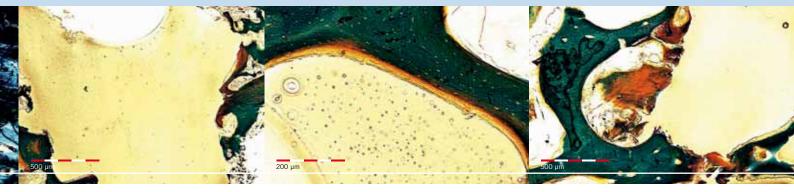
Clinical testing and histological examination:

Technical University of Dresden, Faculty of Medicine, Hospital and Policlinic for Oral and Maxillofacial Surgery

Prof. Dr. Dr. Uwe Eckelt (M.D.) Dr. Eckard Pilling (M.D.) Dr. Ronald Mai (M.D.) Mechanical basic research:

Technical University of Dresden, Faculty of Medicine, Policlinic for Prosthetic Dentistry

Prof. Dr. Bernd Reitemeier (M.D.) Dr. Gert Richter (engineer) Heike Meißner (degreed engineer)



32 days after insertion of the SonicPin Rx

3 months after the operation

Another image also taken 3 months after the operation

## Important questions & answers

# *Does SonicPin Rx liquefaction heat up the tissue around the pin?*

Temperature increase is minimal and disappears within seconds. Therefore, no pain or even necroses could be observed.

## Does the treatment cause traumatization?

No. Clinical experience supports the following statements:

- Neither bone destruction nor bone absorption as a result of thermal damage.
- Intact bone structures at the pin implantation site.
- No disadvantages 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 pilot hole.

#### Indications

- Neurosurgery
- Syndrome patients (e.g. Apert's, Crouzon's)
- Pediatric traumas and craniofacial surgery
- Central and lateral midface traumata in the non load-baring area:
  - Tripoid fractures
  - Fontobasal fractures
  - Isolated orbital floor fractures
  - Nasoethmoidal fractures

## 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<sup>®</sup> is a modular and flexible system, fully compatible with KLS Martin's Resorb-x<sup>®</sup> range of plates and meshes, so all SonicPins Rx can be freely combined with any plate or mesh product. Needless to say, the entire system has been validated. It carries the CE-mark and has obtained FDA approval.





### Plates and meshes

- SonicWeld Rx<sup>®</sup> is based on the KLS Martin Group's Resorb-x<sup>®</sup> product range. A multitude of different mesh forms and designs give users a maximum of application flexibility.
- 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.
- The special "rounded edge" geometry additionally supports a body-compatible degradation process.
- This range of products is covered extensively on pages 14-22.



## 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 at 2 bar).
- All components are easily replaceable.
- The angled sonotrode 52-501-02 permits safe work in regions difficult to access, such as the lateral tooth region.



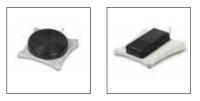
## Smoothening sonotrodes

- Guarantee perfect adaptation of the membrane to the bone surface
- · Several membranes can be welded together to form a unit



## SonicWelder Rx

- The micro-vibrations generated by a defined ultrasonic frequency cause the pin's outer surface to melt.
  As a result, the SonicPin Rx simply glides into the predrilled hole.
- Various pre-programmed application stages, together with optional manual adjustment, allow the surgeon to master any surgical task. Easy to operate, thanks to the user-friendly menu interface.



- Activation by round foot switch 52-500-02-04 (included).
- Optionally:

Rectangular foot switch 52-500-04-04 with reduced actuation resistance (please order separately).

# Complete & flexible

# The system components

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









Pilot drills

# Pilot drill for the angle unit

	Category	Item Number
1	for 1.6 mm SonicPins Rx	•
¥.,	1.0 x 20 mm, stop 5 mm	52-509-05-07
Į.	1.0 x 20 mm, stop 6 mm	52-509-06-07
0	for 2.1 mm SonicPins Rx	•
4	1.6 x 20 mm, stop 5 mm	52-515-05-07
1	1.6 x 20 mm, stop 6 mm	52-515-06-07
ų.,	1.6 x 20 mm, stop 10 mm	52-515-10-07
N	Gliding hole drill	
1	2.1 x 24 x 12 mm	52-522-10-07
1		



Drill bits

	Stryker attachment	Dimensions (mm)	ltem Number
A	for 1.6 mm	1.0 x 50 x 3	52-510-03-07
Ĥ.	SonicPins Rx	1.0 x 50 x 4	52-510-04-07
¥		1.0 x 50 x 5	52-510-05-07
Ħ		1.0 x 50 x 6	52-510-06-07
		1.0 x 50 x 7	52-510-07-07
		1.0 x 50 x 8	52-510-08-07
	for 2.1 mm	1.6 x 50 x 3	52-516-03-07
	SonicPins Rx	1.6 x 50 x 4	52-516-04-07
Ч		1.6 x 50 x 5	52-516-05-07
		1.6 x 50 x 6	52-516-06-07
		1.6 x 50 x 8	52-516-08-07
		1.6 x 50 x 10	52-516-10-07
ß	For BOS-Drill	Dimensions (mm)	ltem Number
	for 1.6 mm	1.0 x 40 x 3	52-610-03-07
÷	SonicPins Rx	1.0 x 40 x 4	52-610-04-07
Ħ		1.0 x 40 x 5	52-610-05-07
		1.0 x 40 x 8	52-610-08-07
	for 2.1 mm	1.6 x 40 x 3	52-616-03-07
	SonicPins Rx	1.6 x 40 x 4	52-616-04-07
U		1.6 x 40 x 5	52-616-05-07
		1.6 x 40 x 10	52-616-10-07

#### SonicWelder Rx

SonicWelder Rx®		
Designation/Unit	Quantity	Item Number
SonicWelder Rx basic set	1 unit	52-500-00-04
consisting of:		
SonicWelder Rx®	1 unit	-
Round foot switch	1 unit	52-500-02-04
Handpiece	1 unit	52-500-03-04
Sonotrode, straight	1 unit	52-501-01-04
Open-ended wrench*	1 unit	52-502-01-04
*for the sonotrode		

# SonicPins Rx

_	Dimensions (mm)	Item Number (SU=2/pack)	Item Number (SU=5/pack)
O	1.6 x 4	52-516-24-04	52-516-54-04
Æ	1.6 x 5	52-516-25-04	52-516-55-04
Ħ	1.6 x 6	52-516-26-04	52-516-56-04
4	1.6 x 7	52-516-27-04	52-516-57-04
	2.1 x 4	52-521-24-04	52-521-54-04
	2.1 x 5	52-521-25-04	52-521-55-04
	2.1 x 7	52-521-27-04	52-521-57-04
	2.1 x 9	52-521-29-04	52-521-59-04





Xcelsior water bath

Xcelsior water bath			
Category	Scope	Item Number	
Water bath	complete	52-400-10-04	
consisting of:			
Heating unit	separate	-	
Water container	separate	52-400-12-04	
Cover	separate	52-400-13-04	



## Bos Drill

BOS Drill	
Category	Item number
BOS Drill w/o battery pack	50-800-03-04
Battery pack, sterile (10 units)	50-800-02-04



Storage tray, incl. component tray

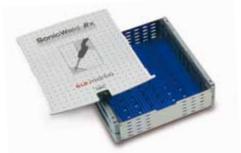
#### Trav for Minicat contain

Item Number
55-015-30-01
ncl. lid
55-963-51-04
55-969-44-04



MicroStop®-MiniSet-Container

Storage and sterilization container for dental st	
Category	Item Number
MicroStop <sup>®</sup> MiniSet container	55-861-60-04
Ext. dimensions 310 x 189 x 85 mm	(L x W x H)
Int. dimensions 283 x 177 x 60 mm	(L x W x H)



Storage and processing tray

l processing tray

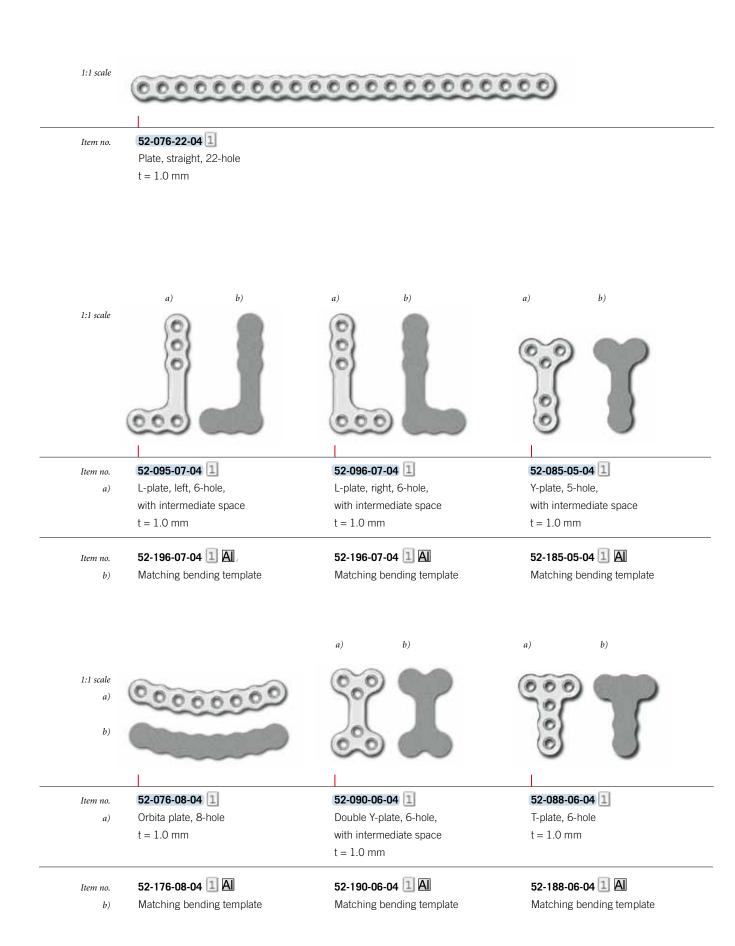
Category	Item Number
Storage and processing tray complete	55-969-42-04
consisting of:	
Storage and processing tray without lid, separate	55-969-28-04
Lid for storage tray, separate	55-963-28-04

Caution: For large sterilizers only!

# The system components

Different requirements, different materials. Always right: SonicWeld  $Rx^{\circ}$  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. A perfect match.

<i>t</i> =	VE/unit	STERILE R	Aluminium
1:1 scale a)	0000	00 00	00 00
<i>b</i> )			
Item no.	52-080-04-04 1	52-082-04-04 1	
a)	Plate, straight, 4-hole t = 0.8 mm	Plate, straight, 4-hole, with intermediate space t = 0.8 mm	
Item no.	52-075-04-04 1	52-077-04-04 1	52-076-04-04 1
<i>a</i> )	Plate, straight, 4-hole t = 1.0 mm	Plate, straight, 4-hole, with intermediate space t = 1.0 mm	Plate, straight, 4-hole, with intermediate space (Magdeburg) t = 1.0 mm
Item no.	52-175-04-04 <b>1</b> A	52-177-04-04 <b>1</b> A	52-176-04-04 <b>1</b> A
<i>b</i> )	Matching bending template	Matching bending template	Matching bending template
		a) b)	a) b)
1:1 scale		8	8
<i>a</i> )	00000000		0
<i>b</i> )		000	000
Item no.	52-075-08-04 1	52-095-06-04 1	52-096-06-04 1
<i>a</i> )	Plate, straight, 8-hole t = 1.0 mm	L-plate, left, 6-hole with intermediate space	L-plate, right, 6-hole with intermediate space
		t = 1.0  mm	t = 1.0  mm
Item no.	52-175-08-04 🔟 Ă	52-196-06-04 🔟 🖪	52-196-06-04 🔟 🖪
b)	Matching bending template	Matching bending template	Matching bending template



## **Resorbable Meshes and Templates**

0	0		0	0
0	0	0	0	0
0	0	0	0	0
0	0	0	0	0
0	0	0	0	0

1:1 scale

52-303-25-04 1

Mesh plate, 26 x 26 mm t = 0.3 mm

**52-306-25-04** 1 Mesh plate, 26 x 26 mm t = 0.6 mm

52-310-25-04 1

t = 1.0 mm

Mesh plate, 26 x 26 mm

# 52-303-50-04 1

Mesh plate, 51 x 51 mm t = 0.3 mm

# 52-306-50-04 1

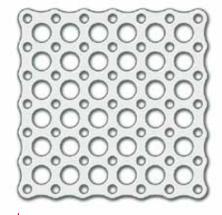
Mesh plate, 51 x 51 mm t = 0.6 mm

# 52-308-50-04 1

Mesh plate, 51 x 51 mm t = 0.8 mm

## 52-310-50-04 1

Mesh plate, 51 x 51 mm t = 1.0 mm



1:1 scale

**52-303-26-04** 1 Mesh flex., 29 x 29 mm t = 0.3 mm

# **52-306-26-04** 1 Mesh flex., 29 x 29 mm

t = 0.6 mm

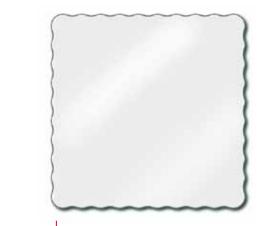
**52-303-51-04** 1 Mesh flex., 51 x 51 mm t = 0.3 mm

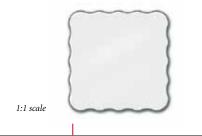
# 52-306-51-04 1

Mesh flex., 51 x 51 mm t = 0.6 mm

# 52-310-53-04 1

Mesh flex., 51 x 51 mm t = 0.8 mm





**52-303-28-04** 1 Sheet, 26 x 26 mm t = 0.3 mm

52-306-28-04 1

Sheet, 25 x 25 mm t = 0.6 mm

# 52-303-52-04 1

Sheet, 51 x 51 mm t = 0.3 mm

# 52-306-52-04 1

Sheet, 51 x 51 mm t = 0.6 mm

# 52-310-52-04 1

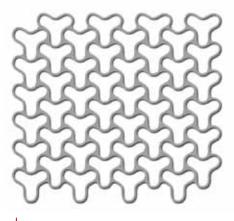
Sheet, 51 x 51 mm

t = 1.0 mm

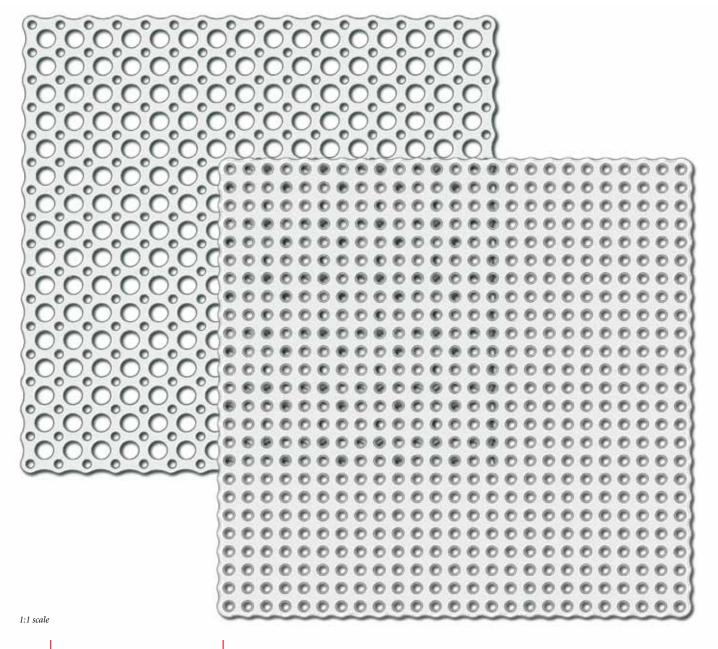


1:1 scale

**52-313-25-04** 1 A Bending template, 25 x 25 mm



**52-313-50-04 1 A** Bending template, 50 x 50 mm

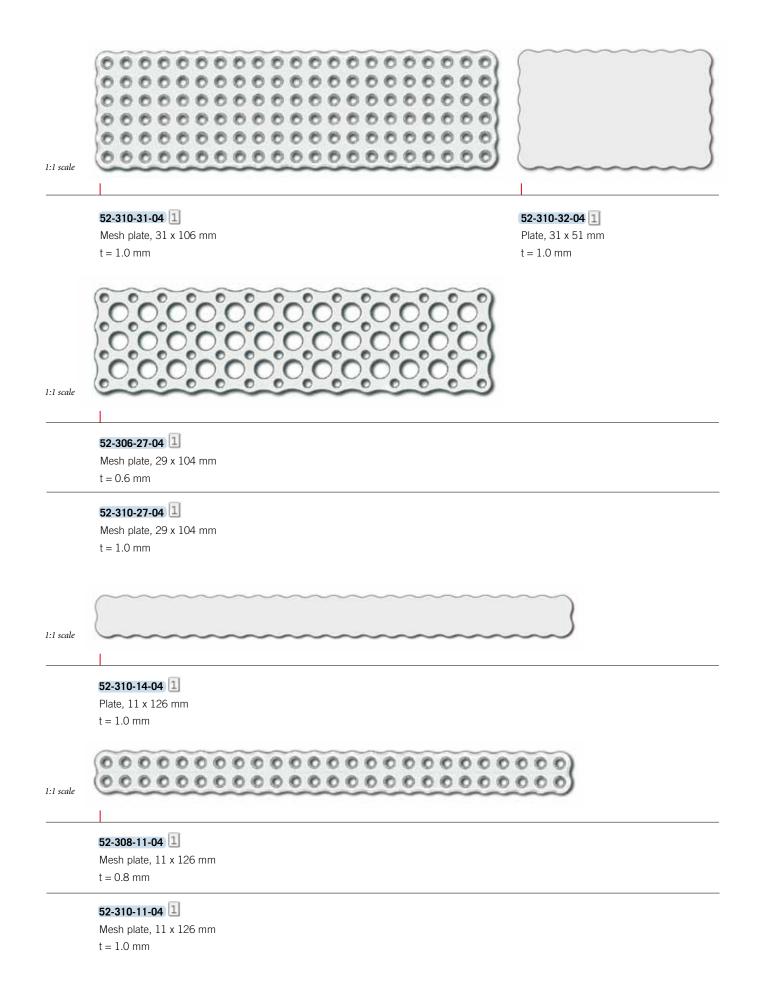


**52-306-12-04** 1 Mesh flex., 126 x 126 mm

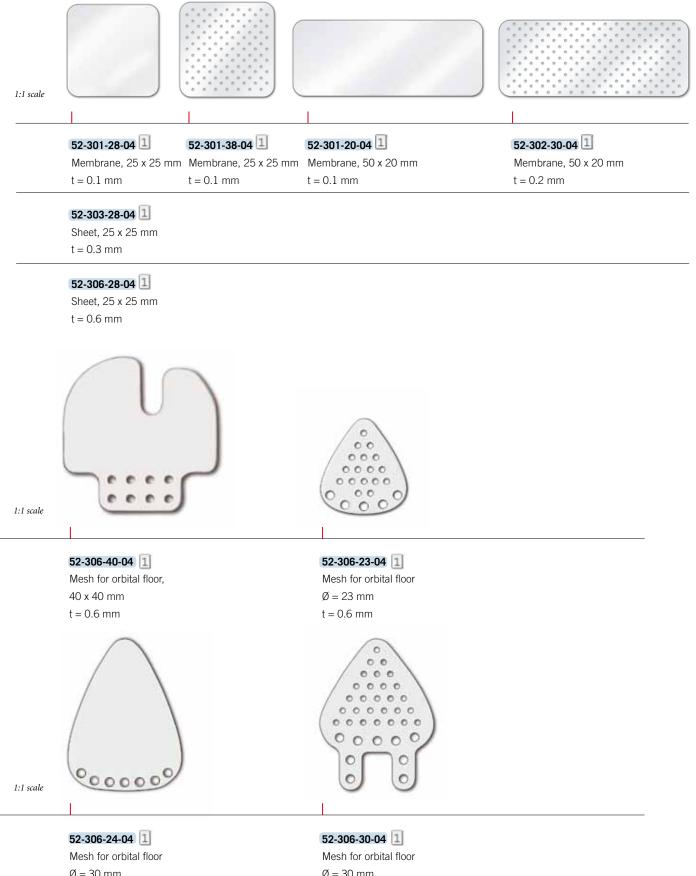
t = 0.6 mm

52-310-12-04 1

Mesh flex., 126 x 126 mm t = 1.0 mm **52-310-13-04** Mesh plate, 126 x 126 mm t = 1.0 mm

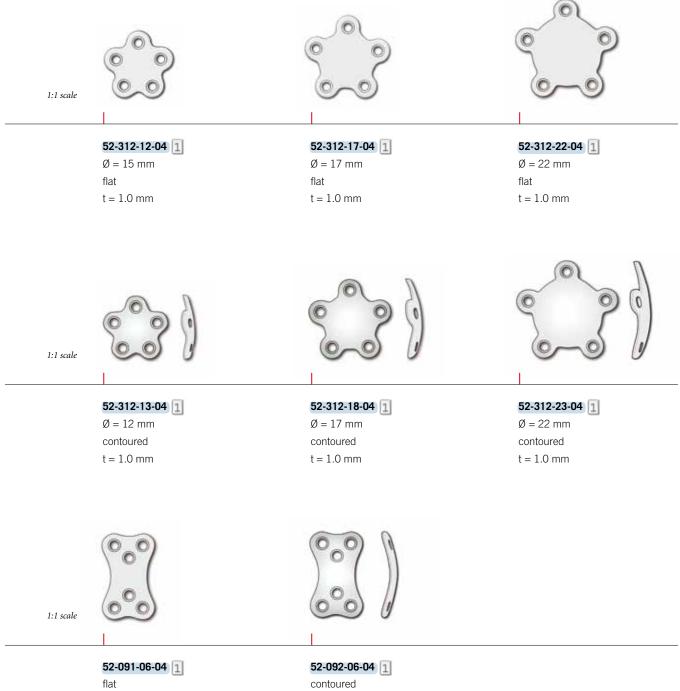


# **Resorbable Meshes**



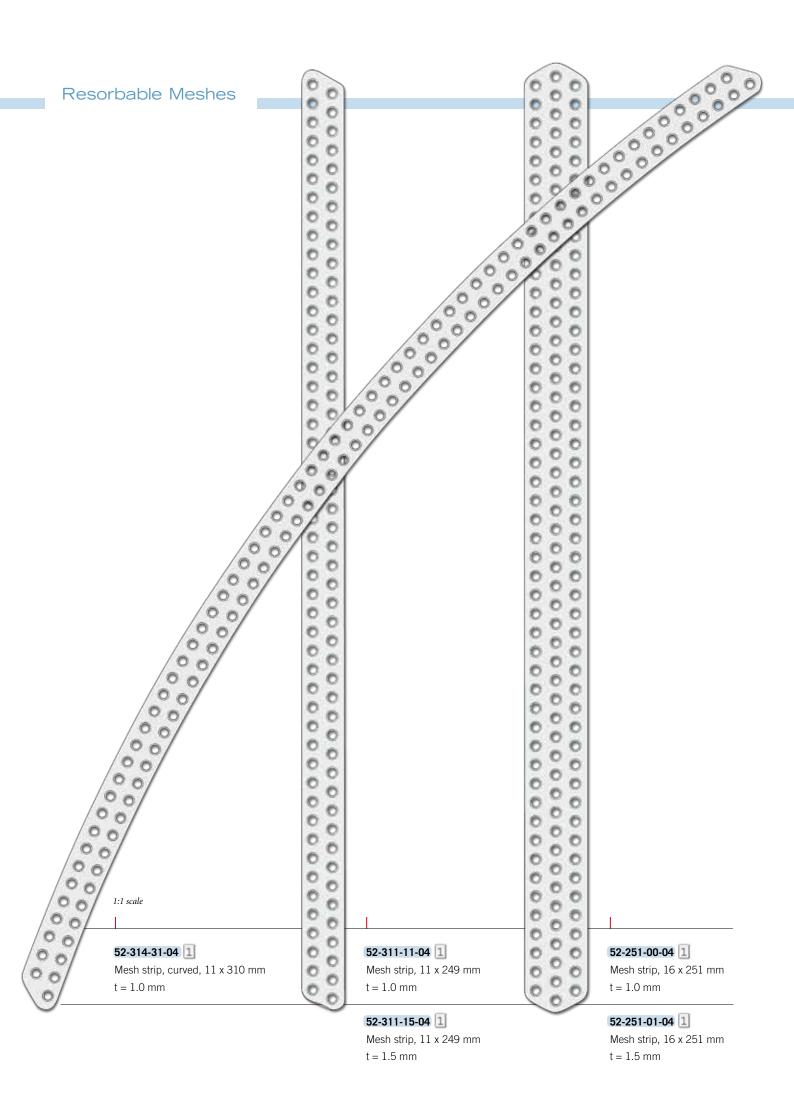
 $\emptyset = 30 \text{ mm}$ t = 0.6 mm

 $\emptyset = 30 \text{ mm}$ t = 0.6 mm



t = 1.0 mm

t = 1.0 mm



# If you still have any questions...

...we will be glad to answer them anytime, for example with additional information in the form of product brochures and a CD-ROM that vividly describe and illustrate the SonicWeld  $Rx^*$  principle – exactly as it works in practice. Of course, you can also reach us personally, either by e-mail or through our customer hotline.

## Additional product brochures and information materials



SonicWeld Rx<sup>®</sup> CD-ROM



SonicWeld Rx<sup>®</sup> Dental Innovative Bone Regeneration



BOS Driver & Drill

Customer hotline: +49 7461 706216 E-mail: sonicweld-rx@klsmartin.com Website: www.sonicweldrx.com



The KLS Martin SonicWeld Rx<sup>®</sup> solution is based on the BoneWelding<sup>®</sup> technology<sup>1</sup> protected by the industrial property rights of WoodWelding AG, Switzerland, and has been licensed by this company. <sup>1)</sup>"BoneWelding<sup>®</sup> is a registered Swiss trademark

#### **KLS Martin Group**

Karl Leibinger GmbH & Co. KG 78570 Mühlheim · Germany Tel. +49 7463 838-0 info@klsmartin.com

KLS Martin GmbH + Co. KG 79224 Umkirch · Germany Tel. +49 7665 9802-0 info@klsmartin.com

Stuckenbrock Medizintechnik GmbH 78532 Tuttlingen · Germany Tel. +49 7461 16 58 80 verwaltung@stuckenbrock.de

Rudolf Buck GmbH 78570 Mühlheim · Germany Tel. +49 7463 99 516-30 info@klsmartin.com KLS Martin France SARL 68000 Colmar · France Tel. +33 3 8921 6601 france@klsmartin.com

Martin Italia S.r.I. 20059 Vimercate (MB) · Italy Tel. +39 039 60 56 731 italia@klsmartin.com

Martin Nederland/Marned B.V. 1270 AG Huizen · The Netherlands Tel. +31 35 523 45 38 nederland@klsmartin.com

KLS Martin UK Ltd. Reading RG1 3EU · United Kingdom Tel. +44 1189 000 570 uk@klsmartin.com Nippon Martin K.K. Osaka 541-0046 · Japan Tel. +81 662 28 90 75 nippon@klsmartin.com

KLS Martin L.P. Jacksonville, FI 32246 · USA Tel. +1 904 641 77 46 usa@klsmartin.com

Gebrüder Martin GmbH & Co. KG Representative Office 121471 Moscow · Russia Tel. +7 499 792-76-19 russia@klsmartin.com

Gebrüder Martin GmbH & Co. KG Representative Office 201203 Shanghai · China Tel. +86 21 2898 6611 china@klsmartin.com Gebrüder Martin GmbH & Co. KG Representative Office Dubai · United Arab Emirates Tel. +971 4 454 16 55 middleeast@klsmartin.com

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