SonicWeld *Rx*®

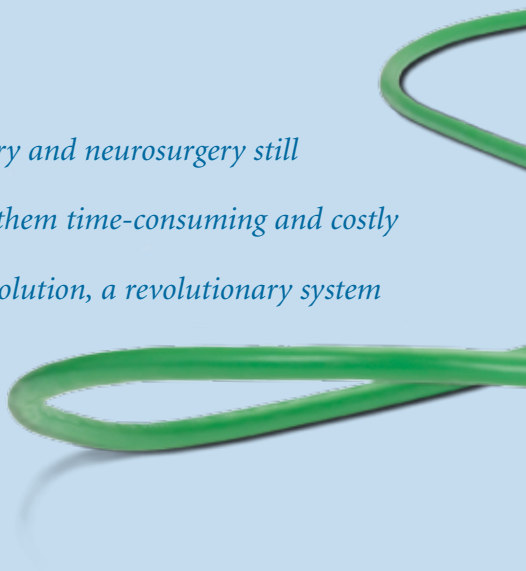
A new era in craniofacial osteosynthesis

KLS martin GROUP

SonicWeld Rx® – 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® 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® – 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® system. It is used to weld specially designed SonicPins Rx directly into the bone structures.

Contents:

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.

1

The new form of resorption

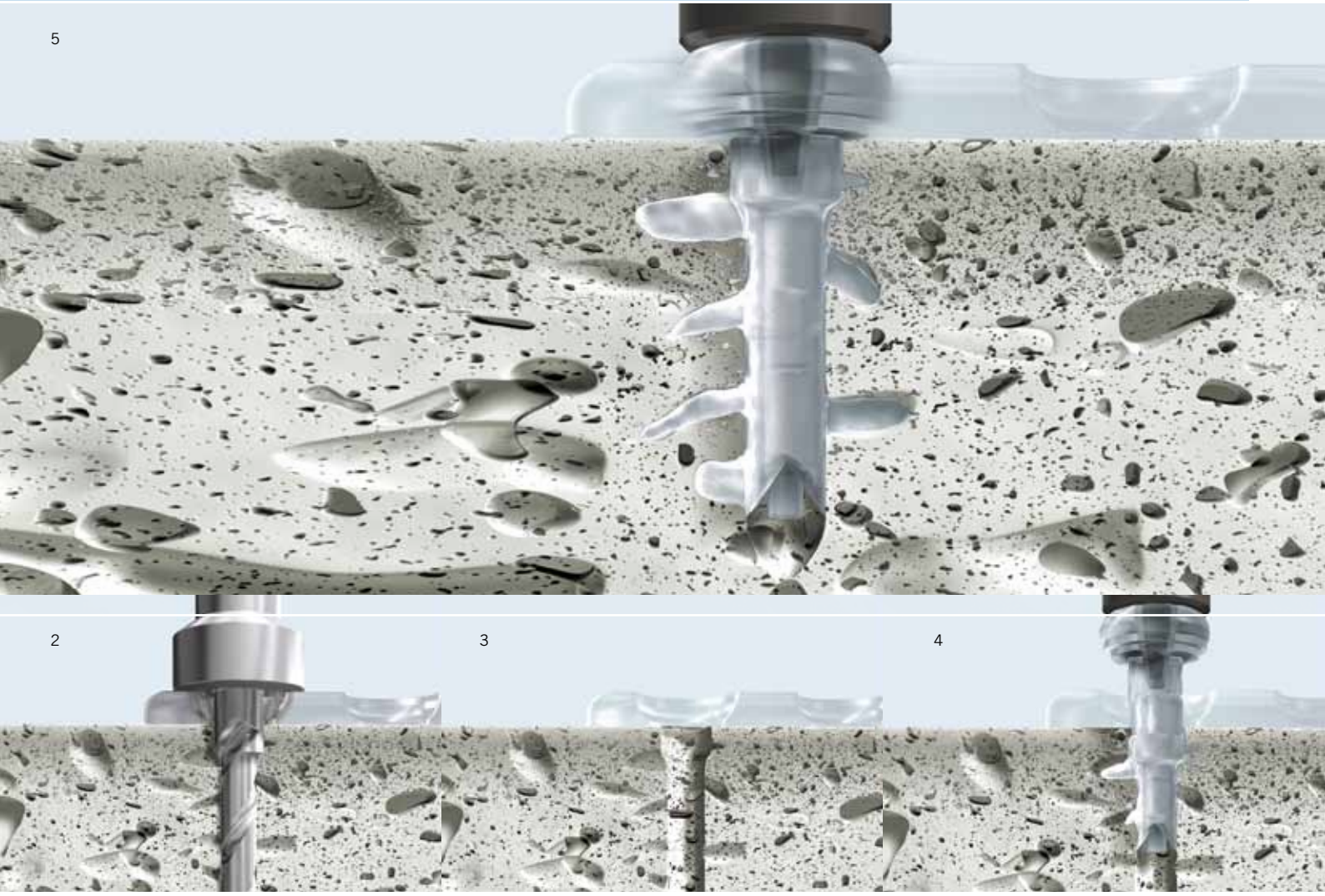
The welding-in process gives the SonicPins Rx primary stability to a degree previously unknown in resorbable implants. As a result, the three-dimensional reconstruction is significantly more rigid, especially where major, large-surface interventions are concerned.
Besides, SonicWeld Rx® permits firm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



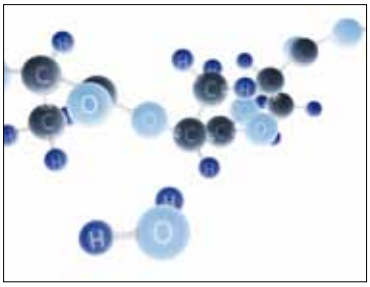
Osteosynthesis with SonicWeld Rx® – a very simple procedure: Adapt the plate/mesh (1), predrill the hole (2) and insert the SonicPin Rx (3). The sonotrode's ultrasonic vibrations cause the SonicPin Rx to melt on the surface and glide into the predrilled hole (4). In this process, the SonicPin Rx combines 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® is based on our Resorb-x® 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.*



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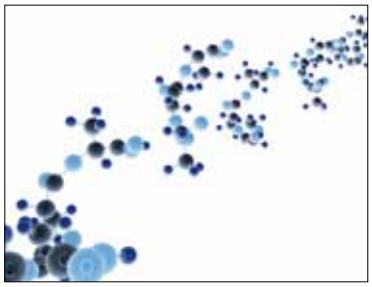

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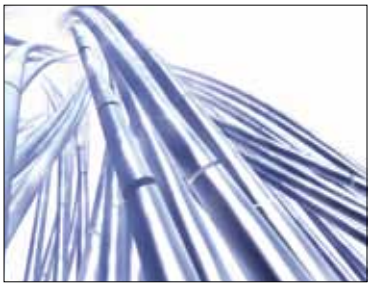


4

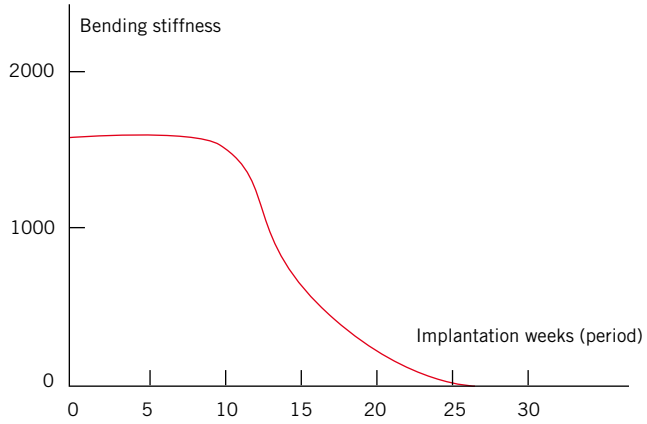
The advantages

- **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 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® 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

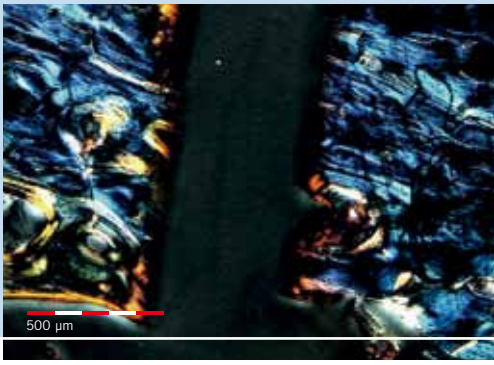
The PDLLA material's complex polymer chains (1) absorb the water contents (H_2O molecules) of surrounding body fluids (2) – a process called "hydrolysis". The stored water then initiates the degradation process, continuously breaking down the long polymer chains into ever-shorter molecular chains (3, 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:

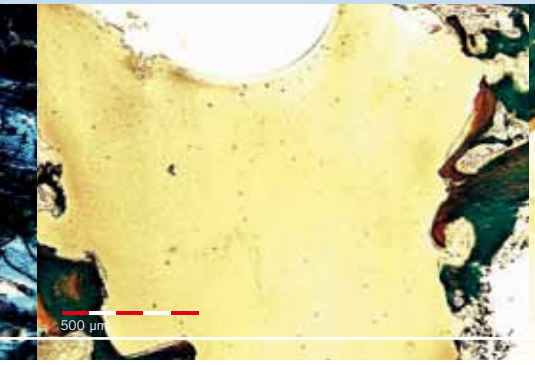
Technical University of Dresden, Faculty of Medicine, Hospital and Policlinic for Oral and Maxillofacial Surgery

Prof. Dr. Dr. Uwe Eckelt (M.D.)
Dr. Eckard Pilling (M.D.)
Dr. Ronald Mai (M.D.)

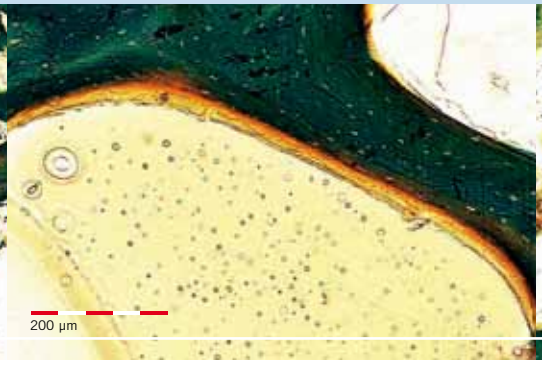
Mechanical basic research:

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

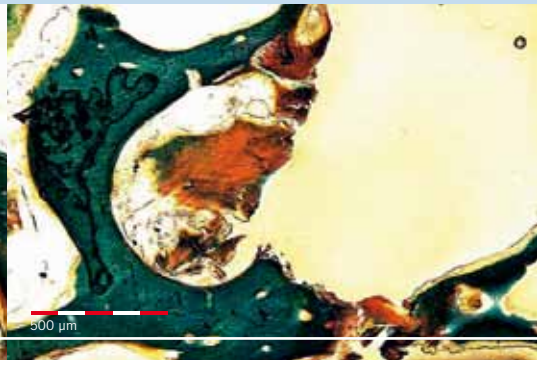
Prof. Dr. Bernd Reitemeier (M.D.)
Dr. Gert Richter (engineer)
Heike Meißner (degreed engineer)



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® is a modular and 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 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® is based on the KLS Martin Group's Resorb-x® 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.

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.

Smoothening sonotrodes

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

- 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).

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

SonicWelder Rx

Pilot drills

Drill bits

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)*
1.6 x 4	52-516-24-04	52-516-54-04
1.6 x 5	52-516-25-04	52-516-55-04
1.6 x 6	52-516-26-04	52-516-56-04
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

Pilot drill for the angle unit with dental attachment

Category	Item Number
for 1.6 mm SonicPins Rx ●	
1.0 x 20 mm, stop 5 mm	52-509-05-07
1.0 x 20 mm, stop 6 mm	52-509-06-07
for 2.1 mm SonicPins Rx ●	
1.6 x 20 mm, stop 5 mm	52-515-05-07
1.6 x 20 mm, stop 6 mm	52-515-06-07
1.6 x 20 mm, stop 10 mm	52-515-10-07
Gliding hole drill	
2.1 x 24 x 12 mm	52-522-10-07

Drill bits for SonicPins RX

Stryker attachment	Dimensions (mm)	Item Number
for 1.6 mm	1.0 x 50 x 3	52-510-03-07
SonicPins Rx	1.0 x 50 x 4	52-510-04-07
	1.0 x 50 x 5	52-510-05-07
	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
	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

For BOS-Drill	Dimensions (mm)	Item 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
	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
	1.6 x 40 x 5	52-616-05-07
	1.6 x 40 x 10	52-616-10-07

BOS Drill

Xcelsior water bath

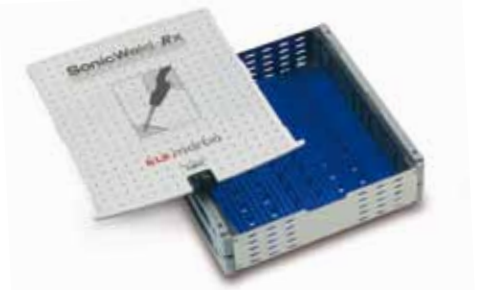
Xcelsior water bath

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

Storage tray, incl. component tray

Tray for Miniset container

Category	Item Number
Tray for MiniSet container	55-015-30-01
277 x 171 x 54 mm (L x W x H) incl. lid	
Storage component tray	
Sliding cover, aluminium	55-963-51-04
Component tray	55-969-44-04



Storage and processing tray

Storage and 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!

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

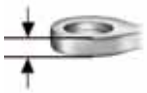
MicroStop®-MiniSet-Container

Storage and sterilization container for dental sterilizer

Category	Item Number
MicroStop® 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)	

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. All plates are depicted at a 1:1 scale, all meshes at a 1:2 scale. A perfect match.

t =  1 VE/unit STERILE R Al Aluminium

1:1 scale

a) 

b)

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
a)	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** 1 Al	**52-177-04-04** 1 Al	**52-176-04-04** 1 Al
b)	Matching bending template	Matching bending template	Matching bending template

1:1 scale

a) 

b) 

a) b) 

a) b) 

Item no.	**52-075-08-04** 1	**52-095-06-04** 1	**52-096-06-04** 1
a)	Plate, straight, 8-hole t = 1.0 mm	L-plate, left, 6-hole with intermediate space t = 1.0 mm	L-plate, right, 6-hole with intermediate space t = 1.0 mm
Item no.	**52-175-08-04** 1 Al	**52-196-06-04** 1 Al	**52-196-06-04** 1 Al
b)	Matching bending template	Matching bending template	Matching bending template

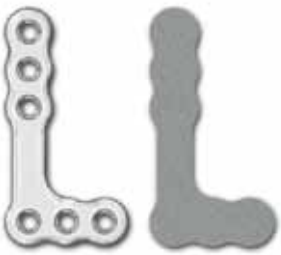
1:1 scale

Item no. **52-076-22-04** 1

Plate, straight, 22-hole
t = 1.0 mm

a) b)

1:1 scale



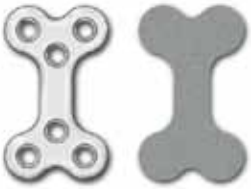
Item no.	**52-095-07-04** 1	**52-096-07-04** 1	**52-085-05-04** 1
a)	L-plate, left, 6-hole, with intermediate space t = 1.0 mm	L-plate, right, 6-hole, with intermediate space t = 1.0 mm	Y-plate, 5-hole, with intermediate space t = 1.0 mm
Item no.	**52-196-07-04** 1 Al	**52-196-07-04** 1 Al	**52-185-05-04** 1 Al
b)	Matching bending template	Matching bending template	Matching bending template

a) b)

1:1 scale

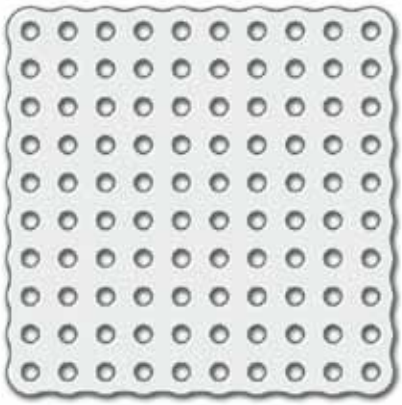
a)

b)



Item no.	**52-076-08-04** 1	**52-090-06-04** 1	**52-088-06-04** 1
a)	Orbita plate, 8-hole t = 1.0 mm	Double Y-plate, 6-hole, with intermediate space t = 1.0 mm	T-plate, 6-hole t = 1.0 mm
Item no.	**52-176-08-04** 1 Al	**52-190-06-04** 1 Al	**52-188-06-04** 1 Al
b)	Matching bending template	Matching bending template	Matching bending template

1:1 scale



52-303-25-04 1
Mesh plate, 26 x 26 mm
t = 0.3 mm

52-303-50-04 1
Mesh plate, 51 x 51 mm
t = 0.3 mm

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

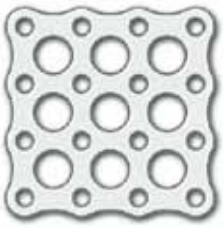
52-306-50-04 1
Mesh plate, 51 x 51 mm
t = 0.6 mm

52-308-50-04 1
Mesh plate, 51 x 51 mm
t = 0.8 mm

52-310-25-04 1
Mesh plate, 26 x 26 mm
t = 1.0 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

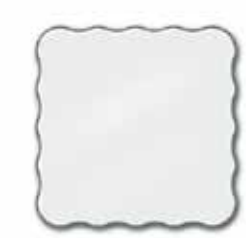
52-303-51-04 1
Mesh flex., 51 x 51 mm
t = 0.3 mm

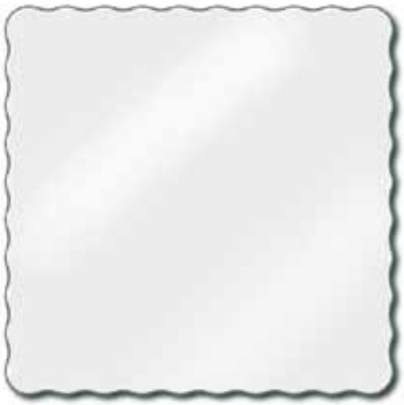
52-306-26-04 1
Mesh flex., 29 x 29 mm
t = 0.6 mm

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

1:1 scale





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

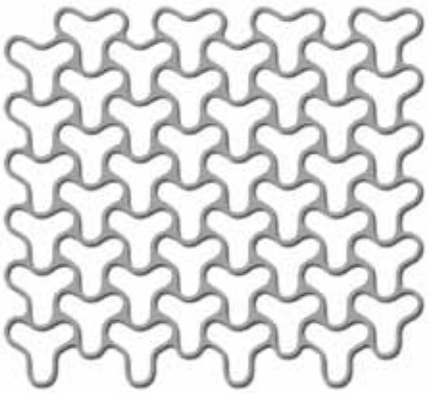
52-303-52-04 1
Sheet, 51 x 51 mm
t = 0.3 mm

52-306-28-04 1
Sheet, 25 x 25 mm
t = 0.6 mm

52-306-52-04 1
Sheet, 51 x 51 mm
t = 0.6 mm

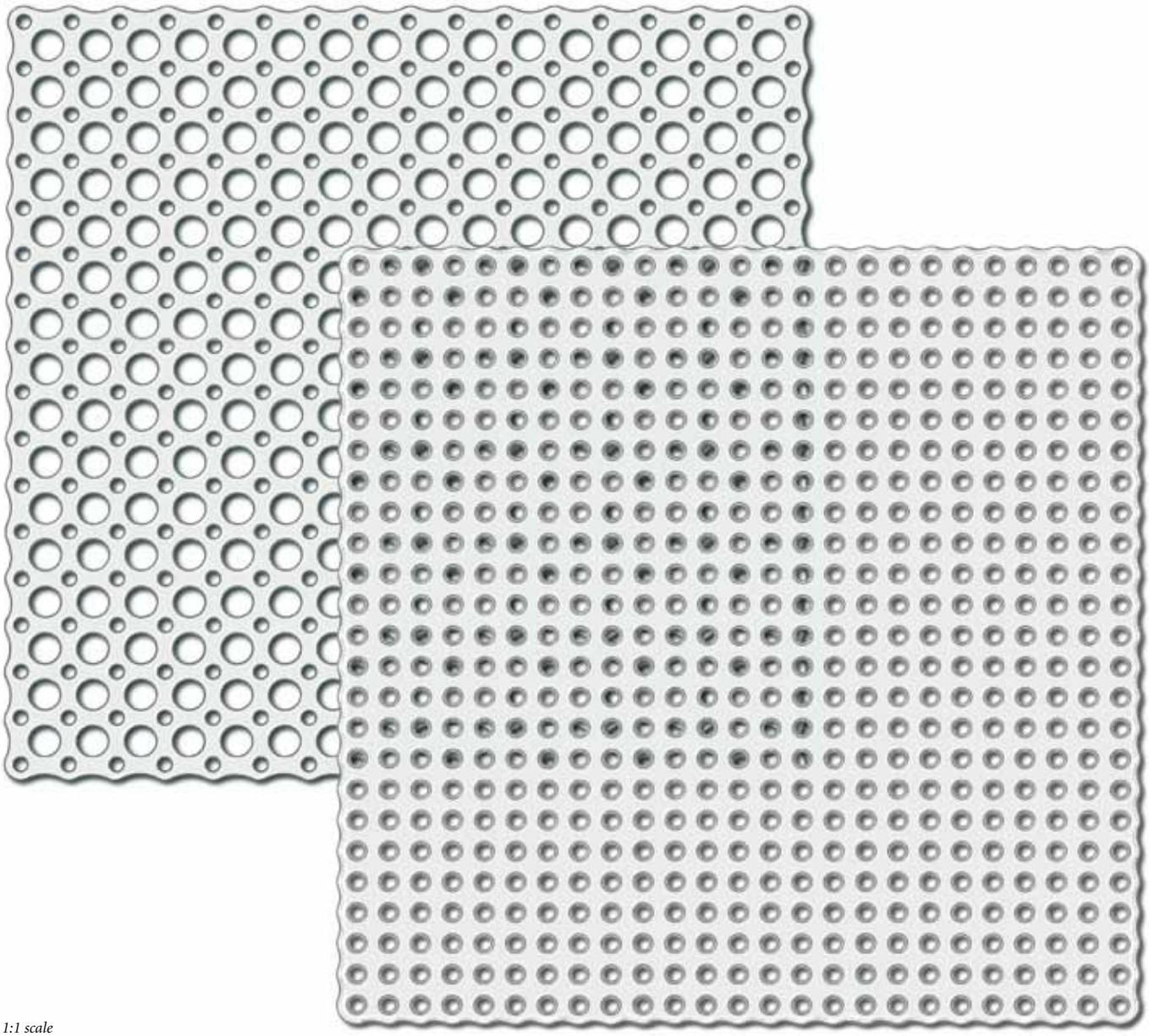
52-310-52-04 1
Sheet, 51 x 51 mm
t = 1.0 mm

1:1 scale



52-313-25-04 1 Al
Bending template, 25 x 25 mm

52-313-50-04 1 Al
Bending template, 50 x 50 mm



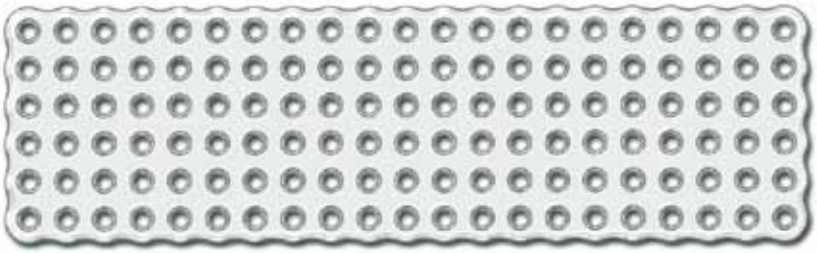
1:1 scale

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 1
Mesh plate, 126 x 126 mm
t = 1.0 mm

1:1 scale



52-310-31-04 1
Mesh plate, 31 x 106 mm
t = 1.0 mm

52-310-32-04 1
Plate, 31 x 51 mm
t = 1.0 mm

1:1 scale

52-306-27-04 1
Mesh plate, 29 x 104 mm
t = 0.6 mm

52-310-27-04 1
Mesh plate, 29 x 104 mm
t = 1.0 mm

1:1 scale

52-310-14-04 1
Plate, 11 x 126 mm
t = 1.0 mm

1:1 scale

52-308-11-04 1
Mesh plate, 11 x 126 mm
t = 0.8 mm

52-310-11-04 1
Mesh plate, 11 x 126 mm
t = 1.0 mm

Resorbable Meshes

1:1 scale

52-301-28-04 1
Membrane, 25 x 25 mm
t = 0.1 mm

52-301-38-04 1
Membrane, 25 x 25 mm
t = 0.1 mm

52-301-20-04 1
Membrane, 50 x 20 mm
t = 0.1 mm

52-302-30-04 1
Membrane, 50 x 20 mm
t = 0.2 mm

52-303-28-04 1
Sheet, 25 x 25 mm
t = 0.3 mm

52-306-28-04 1
Sheet, 25 x 25 mm
t = 0.6 mm

1:1 scale

52-306-40-04 1
Mesh for orbital floor,
40 x 40 mm
t = 0.6 mm

52-306-23-04 1
Mesh for orbital floor
Ø = 23 mm
t = 0.6 mm

1:1 scale

52-306-24-04 1
Mesh for orbital floor
Ø = 30 mm
t = 0.6 mm

52-306-30-04 1
Mesh for orbital floor
Ø = 30 mm
t = 0.6 mm

1:1 scale

52-312-12-04 1
Ø = 15 mm
flat
t = 1.0 mm

52-312-17-04 1
Ø = 17 mm
flat
t = 1.0 mm

52-312-22-04 1
Ø = 22 mm
flat
t = 1.0 mm

1:1 scale

52-312-13-04 1
Ø = 12 mm
contoured
t = 1.0 mm

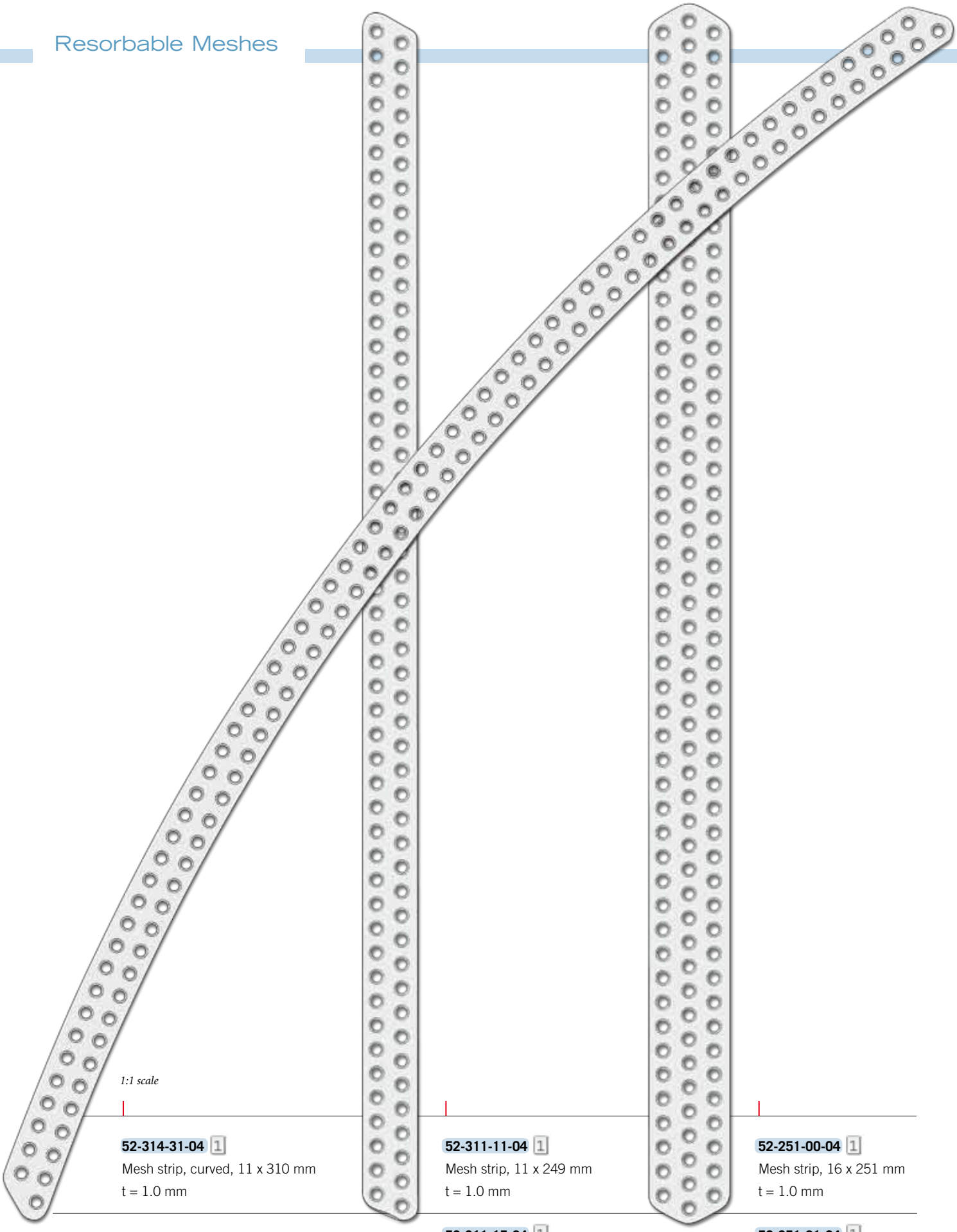
52-312-18-04 1
Ø = 17 mm
contoured
t = 1.0 mm

52-312-23-04 1
Ø = 22 mm
contoured
t = 1.0 mm

1:1 scale

52-091-06-04 1
flat
t = 1.0 mm

52-092-06-04 1
contoured
t = 1.0 mm



1:1 scale

52-314-31-04 1
Mesh strip, curved, 11 x 310 mm
t = 1.0 mm

52-311-11-04 1
Mesh strip, 11 x 249 mm
t = 1.0 mm

52-311-15-04 1
Mesh strip, 11 x 249 mm
t = 1.5 mm

52-251-00-04 1
Mesh strip, 16 x 251 mm
t = 1.0 mm

52-251-01-04 1
Mesh strip, 16 x 251 mm
t = 1.5 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®
CD-ROM

SonicWeld Rx® Dental
Innovative Bone
Regeneration

BOS Driver & Drill

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

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