A new era in craniofacial osteosynthesis
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.

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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.

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.
• **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.

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).
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 by hydrolysis is predictable. There are no crystalline residues, no tissue irritations. All constituents are completely discharged through the metabolic channels.

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.

SonicWeld Rx® is based on our Resorb-x® product range, consisting of the same base material: Poly-D and L-Lactic Acid (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® 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 (H₂O 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.

Clinical testing and histological examination:
Technical University of Dresden, Faculty of Medicine, Hospital and Polyclinic 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, Polyclinic for Prosthetic Dentistry
Prof. Dr. Bernd Reitemeier (M.D.)
Dr. Gert Richter (engineer)
Heike Meißner (degreed engineer)

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.

Longitudinal section through SonicPin Rx and supporting tissue immediately 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.

Validated & compatible

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.

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.
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 foot switch.

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 foot switch.
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.

### SonicWelder Rx®

<table>
<thead>
<tr>
<th>Designation/Unit</th>
<th>Quantity</th>
<th>Item Number</th>
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</thead>
<tbody>
<tr>
<td>SonicWelder Rx basic set</td>
<td>1 unit</td>
<td>52-500-00-04</td>
</tr>
<tr>
<td>SonicWelder Rx®</td>
<td>1 unit</td>
<td>52-500-02-04</td>
</tr>
<tr>
<td>Foot switch</td>
<td>1 unit</td>
<td>52-500-03-04</td>
</tr>
<tr>
<td>Handpiece</td>
<td>1 unit</td>
<td>52-500-04-04</td>
</tr>
<tr>
<td>Sonotrode, straight</td>
<td>1 unit</td>
<td>52-501-01-04</td>
</tr>
<tr>
<td>Open-ended wrench*</td>
<td>1 unit</td>
<td>52-502-01-04</td>
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</table>

*for the sonotrode

### SonicPins Rx

<table>
<thead>
<tr>
<th>Dimensions (mm)</th>
<th>Item Number (SU = 2/pack)</th>
<th>Item Number (SU = 5/pack)</th>
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</thead>
<tbody>
<tr>
<td>1.6 x 4</td>
<td>52-516-24-04</td>
<td>52-516-54-04</td>
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<tr>
<td>1.6 x 5</td>
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<td>1.6 x 7</td>
<td>52-516-27-04</td>
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<tr>
<td>2.1 x 4</td>
<td>52-521-24-04</td>
<td>52-521-54-04</td>
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<tr>
<td>2.1 x 5</td>
<td>52-521-25-04</td>
<td>52-521-55-04</td>
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<td>2.1 x 7</td>
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<td>2.1 x 9</td>
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### Pilot drill for the angle unit with dental attachment

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<tbody>
<tr>
<td>for 1.6 mm SonicPins Rx</td>
<td>52-509-05-07</td>
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<tr>
<td>1.0 x 20 mm, stop 5 mm</td>
<td>52-509-05-07</td>
</tr>
<tr>
<td>1.0 x 20 mm, stop 6 mm</td>
<td>52-509-06-07</td>
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<tr>
<td>for 2.1 mm SonicPins Rx</td>
<td>52-515-05-07</td>
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<td>1.6 x 20 mm, stop 5 mm</td>
<td>52-515-05-07</td>
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<tr>
<td>1.6 x 20 mm, stop 6 mm</td>
<td>52-515-06-07</td>
</tr>
<tr>
<td>1.6 x 20 mm, stop 10 mm</td>
<td>52-515-10-07</td>
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</table>

<table>
<thead>
<tr>
<th>Dimensions (mm)</th>
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</tr>
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<td>1.6 x 40 x 10</td>
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### Drill bits for SonicPins RX

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<td>1.6 x 20 mm, stop 5 mm</td>
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<tr>
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<td>52-515-06-07</td>
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<tr>
<td>1.6 x 20 mm, stop 10 mm</td>
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<td>1.6 x 40 x 10</td>
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## Xcelsior water bath

<table>
<thead>
<tr>
<th>Category</th>
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<tbody>
<tr>
<td>Water bath</td>
<td>complete</td>
<td>52-400-10-04</td>
</tr>
<tr>
<td>Heating unit</td>
<td>separate</td>
<td>-</td>
</tr>
<tr>
<td>Water container</td>
<td>separate</td>
<td>52-400-12-04</td>
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<tr>
<td>Cover</td>
<td>separate</td>
<td>52-400-13-04</td>
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## BOS Drill

<table>
<thead>
<tr>
<th>Category</th>
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<tbody>
<tr>
<td>BOS Drill w/o battery pack</td>
<td>50-800-03-04</td>
</tr>
<tr>
<td>Battery pack, sterile (10 units)</td>
<td>50-800-02-04</td>
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## Storage and sterilization container for dental sterilizer

<table>
<thead>
<tr>
<th>Category</th>
<th>Item Number</th>
</tr>
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<tbody>
<tr>
<td>MicroStop® MiniSet container</td>
<td>55-861-60-04</td>
</tr>
<tr>
<td>Ext. dimensions 310 x 189 x 85 mm (L x W x H)</td>
<td></td>
</tr>
<tr>
<td>Int. dimensions 283 x 177 x 60 mm (L x W x H)</td>
<td></td>
</tr>
<tr>
<td>Possibly:</td>
<td>Scope</td>
</tr>
<tr>
<td>1 x identification label w. text</td>
<td>1 55-864-01-04</td>
</tr>
<tr>
<td>Logistic frame, red colour for container</td>
<td>1 55-864-12-04</td>
</tr>
<tr>
<td>Identification label MiniSet container w. text</td>
<td>2 55-864-05-04</td>
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</tbody>
</table>

## Tray for Miniset container

<table>
<thead>
<tr>
<th>Category</th>
<th>Item Number</th>
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</thead>
<tbody>
<tr>
<td>Tray for Miniset container</td>
<td>55-015-30-01</td>
</tr>
<tr>
<td>277 x 171 x 54 mm (L x W x H) incl. lid</td>
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## Storage component tray

<table>
<thead>
<tr>
<th>Category</th>
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<tbody>
<tr>
<td>Sliding cover, aluminium</td>
<td>55-963-51-04</td>
</tr>
<tr>
<td>Component tray</td>
<td>55-969-44-04</td>
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</tbody>
</table>
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.

Item no. 52-080-04-04  1
a) Plate, straight, 4-hole
   t = 0.8 mm

Item no. 52-075-04-04  1
a) Plate, straight, 4-hole
   t = 1.0 mm

Item no. 52-082-04-04  1
a) Plate, straight, 4-hole, with intermediate space
   t = 0.8 mm

Item no. 52-077-04-04  1
a) Plate, straight, 4-hole, with intermediate space
   t = 1.0 mm

Item no. 52-175-04-04  1
b) Matching bending template

Item no. 52-076-04-04  1
b) Matching bending template

Item no. 52-080-08-04  1
a) Plate, straight, 8-hole
   t = 1.0 mm

Item no. 52-175-08-04  1
b) Matching bending template

Item no. 52-176-04-04  1
b) Matching bending template

Item no. 52-177-04-04  1
b) Matching bending template

Item no. 52-176-08-04  1
b) Matching bending template
**1:1 scale**

<table>
<thead>
<tr>
<th>Item no.</th>
<th>Description</th>
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<tbody>
<tr>
<td>52-095-07-04</td>
<td>L-plate, left, 6-hole, with intermediate space, t = 1.0 mm</td>
</tr>
<tr>
<td>52-096-07-04</td>
<td>L-plate, right, 6-hole, with intermediate space, t = 1.0 mm</td>
</tr>
<tr>
<td>52-085-05-04</td>
<td>Y-plate, 5-hole, with intermediate space, t = 1.0 mm</td>
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</table>

<table>
<thead>
<tr>
<th>Item no.</th>
<th>Description</th>
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<tbody>
<tr>
<td>52-196-07-04</td>
<td>Matching bending template</td>
</tr>
<tr>
<td>52-196-07-04</td>
<td>Matching bending template</td>
</tr>
<tr>
<td>52-185-05-04</td>
<td>Matching bending template</td>
</tr>
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</table>

**52-076-22-04**

Plate, straight, 22-hole

**t = 1.0 mm**

<table>
<thead>
<tr>
<th>Item no.</th>
<th>Description</th>
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<tbody>
<tr>
<td>52-088-06-04</td>
<td>T-plate, 6-hole, with intermediate space, t = 1.0 mm</td>
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</table>

<table>
<thead>
<tr>
<th>Item no.</th>
<th>Description</th>
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<tbody>
<tr>
<td>52-176-08-04</td>
<td>Matching bending template</td>
</tr>
<tr>
<td>52-190-06-04</td>
<td>Matching bending template</td>
</tr>
<tr>
<td>52-188-06-04</td>
<td>Matching bending template</td>
</tr>
</tbody>
</table>
Resorbable Meshes and Templates

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

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

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

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

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

52-310-50-04
Mesh plate, 51 x 51 mm
t = 1.0 mm

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

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

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

52-306-51-04
Mesh flex., 51 x 51 mm
t = 0.6 mm

52-310-53-04
Mesh flex., 51 x 51 mm
t = 0.8 mm
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Dimensions</th>
<th>Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>52-303-28-04</td>
<td>Sheet, 26 x 26 mm</td>
<td>26 x 26 mm</td>
<td>0.3 mm</td>
</tr>
<tr>
<td>52-306-28-04</td>
<td>Sheet, 25 x 25 mm</td>
<td>25 x 25 mm</td>
<td>0.6 mm</td>
</tr>
<tr>
<td>52-310-52-04</td>
<td>Sheet, 51 x 51 mm</td>
<td>51 x 51 mm</td>
<td>1.0 mm</td>
</tr>
<tr>
<td>52-313-25-04</td>
<td>Bending template, 25 x 25 mm</td>
<td>25 x 25 mm</td>
<td></td>
</tr>
<tr>
<td>52-313-50-04</td>
<td>Bending template, 50 x 50 mm</td>
<td>50 x 50 mm</td>
<td></td>
</tr>
</tbody>
</table>
Resorbable Meshes

52-306-12-04 1
Mesh flex., 126 x 126 mm
\( t = 0.6 \text{ mm} \)

52-310-12-04 1
Mesh flex., 126 x 126 mm
\( t = 1.0 \text{ mm} \)

52-310-13-04 1
Mesh plate, 126 x 126 mm
\( t = 1.0 \text{ mm} \)
Resorbable Meshes

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

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

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

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

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

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

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

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

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

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

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

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

- **52-251-01-04**
  - 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

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Website: www.sonicweldrx.com

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