Creation & Approval

Created on / by / Signature	Checked on / by / Signature	Approved on / by / Signature
05.12.2025 / Maik Schutzbach	05.12.2025 / Christian Elsner	05.12.2025 / Markus Schutzbach
		

Index of Changes

Revision	Date of issue	Description of the change	Revision / language version validated by the Notified Body
1.0	05.12.2025	Released version of the version v5.0_E03 (german), validated by the Notified Body	☐ YES / german ☒ No*

*The Notified Body validated only the German language version. For this reason, the checkbox next to “No” is selected here. The content has not been changed.

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Definition / Introduction

For implantable medical devices (excluding custom-made and investigational devices), the Medical Device Regulation (MDR) requires a summary of safety and clinical performance (SSCP – MDR Chapter III, Article 32 [1]).

This summary report is a summary of the available clinical data as well as other relevant information regarding the safety and clinical performance of the medical device concerned, applying the MDR [1] and the MDCG 2019-9 guideline for manufacturers and notified bodies [2].

The contents of the SSCP shall be derived exclusively from the Technical Documentation (TD) of the product. "Product" shall mean all affected products associated with this SSCP (see Chapter 1.1). For updates, make sure that the summary report corresponds to the current TD of the product in all sections.

1. Device identification and general information

1.1 Product trade name(s)

The product group has the following trade names:

- dev-os Microscrews / Titanium
- dev-os Microscrews / INOX
- dev-os Tenting-Screws / INOX
- dev-os Titanium Pins
- dev-os Titanium Meshes

1.2 Name and address of the manufacturer

devemed GmbH
take-off GewerbePark 30
78579 Neuhausen ob Eck
Germany

1.3 Single Registration Number (SRN) of the manufacturer

DE-MF-000005568

1.4 Unique Identifier SSCP

The SSCP for the Basic-UDI-DIs shown in Chapter 1.5 is controlled by the unique identification of the file name **1.06_SSCP_PG14**.

1.5 Basic UDI-DI

Microscrews / Titanium:	4061644PG1401012Y
Microscrews / INOX:	4061644PG14010232
Pins:	4061644PG1403CX
Meshes:	4061644PG1404CZ

1.6 Nomenclature of the product

1.6.1 UMDNS

Product Group	UMDNS	UMDNS-Nomenclature
Microscrews	16-101	Screw, Bone
Pins	16-085	Pin, Bone
Meshes	16-042	Network

1.6.2 EMDN

Product Group	EMDN	EMDN-Nomenclature
Microscrews	P09120402	Screws
Pins	P09120604	Osteosynthesis Nail-Screw Systems
Meshes	P900206	Metallic Surgical Meshes

1.6.3 GMDN

Product Group	GMDN	GMDN-Nomenclature
Microscrews	56642	Orthopaedic bone screw, non-bioabsorbable, non-sterile
Pins	46645	Membrane fixation tack, non-bioabsorbable
Meshes	46580	Multi-purpose surgical mesh, metallic

1.6.4 MDN, MDS, MDT,

Product Group	EMDN	UMDNS Nomenclature
Microscrews	MDN 1102, MDT 2001, MDT 2011	MDN 1102: Non-active osteo- and orthopaedic implants MDT 2001: Devices manufactured using metal processing MDT 2011: Devices which require packaging, including labelling
Pins	MDN 1102, MDT 2001, MDT 2011	MDN 1102: Non-active osteo- and orthopaedic implants MDT 2001: Devices manufactured using metal processing MDT 2011: Devices which require packaging, including labelling
Meshes	MDN 1102, MDT 2001, MDT 2011	MDN 1102: Non-active osteo- and orthopaedic implants MDT 2001: Devices manufactured using metal processing MDT 2011: Devices which require packaging, including labelling

1.7 Risk class of the product

The classification of medical devices is IIb according to MDR 2017/745, Annex VII, Rule 8
Indents are not applied

1.8 Year in which the first certificate (CE) was issued for the product

Approval status / marketing history	dev-os Microscrews / Titanium	CE marked since 01.09.2020 under MDD
	dev-os Microscrews / INOX	Initial certification under MDR
	dev-os Tenting-Screws / INOX	Initial certification under MDR
	dev-os Titanium Pins	CE marked since 01.09.2020 under MDD 93/42/EEC (Standard Pins) Initial certification under MDR (Solid Pins)
	dev-os Titanium Meshes	Initial certification under MDR

1.9 Authorized representative, if applicable; Name and SRN

Not applicable

1.10 Name of the Notified Body and its identification number

mdc medical device certificate GmbH
Kriegerstrasse 6
70191 Stuttgart
Deutschland/Germany
ID: 0483

2. Intended use of the device

2.1 Intendes use, indications, contraindications, patient group

Intended uses	**dev-os Microscrews (valid for all 3 screw families):** Microscrews for fixing bone grafts and bone graft substitutes for augmentation and/or reconstruction of jaw and facial bones.
	dev-os Titanium Pins: Pins for fixing membranes and meshes during augmentation and/or reconstruction of jaw and facial bones.
	dev-os Titanium Meshes: Meshes for fixing bone grafts and bone graft substitutes for augmentation and/or reconstruction of jaw and facial bones.
Indications	**dev-os Microscrews (valid for all 3 screw families):** Microscrews are indicated for augmentation of bone defects, atrophied bones and malformations in the oral cavity and the maxillomandibular surgical area.
	dev-os Titanium Pins: Pins are indicated for guided bone regeneration for the fixation of membranes and meshes.
	dev-os Titanium Micro-Meshes: • Augmentation of jaw and facial bones • Reconstruction of bone defects and bone malformations in the jaw area
	dev-os Titanium Tenting-Meshes: Tenting meshes are indicated for the augmentation of jaw and facial bones or the reconstruction of bone defects and bone malformations in the jaw area, which take place at the same time as the implantation of dental implants.
Contraindications	**dev-os Microscrews / dev-os Titanium Pins / dev-os Titanium Meshes** The products are contraindicated for all purposes except the described intended use and indication and must not be used outside of dentistry or in direct application by the patient. Furthermore, general medical as well as local, absolute and relative contraindications for dental surgical procedures must be observed. Absolute contraindications: • Active/acute infections in or near the area to be augmented, as well as local or systemic pathological processes (e.g., symptoms such as fever, local inflammation, abscesses) • Diseases or medications that impair bone metabolism and could prevent revascularization of the graft • Insufficient soft tissue coverage, which does not allow for complete coverage of the augmented area. • Patients with proven allergies and/or material intolerances to titanium • Chronic pain patients • Incomplete dentoalveolar growth • Highly uncooperative patients who, due to mental or neurological disorders, are unable to follow the doctor's instructions regarding follow-up care. Relative contraindications: • Systemic and/or metabolic diseases or medical treatments that lead to progressive bone deterioration (e.g., cortisone, immunosuppressants, bisphosphonates, diabetes, etc.) • Drug and alcohol abuse; nicotine consumption • Circulatory disorders • Lack of patient compliance • When used in conjunction with endosseous implants, their contraindications must also be observed.

Residual risks and known side effects	**dev-os Microscrews / dev-os Titanium Pins / dev-os Titanium Meshes** Complications, risks and side effects are more often caused by the surgical procedure than by the implant. • Mucosal or tissue reaction • Skin rash • Loosening of the implant due to insufficient, improper attachment • Implant breakage / swallowing of fragments • Possible nerve or blood vessel damage as a result of the surgical procedure • Increased connective tissue reaction • Complications due to twisting of the screw or injury to tissue/bone due to imprecise placement (*specified only for screws)* • Complications resulting from pin bending or tissue/bone injury caused by imprecise placement (*specified only for pins)* • Complications or injury to the fabric due to sharp edges of the mesh or imprecise placement *(specified only for meshes)* The following complications, risks and/or side effects may occur after implantation: • Severe edema, hematoma formation; pain and swelling • Postoperative bleeding • Infections; wound infection at the donor and/or recipient site • Abscess • Soft tissue/ wound dehiscence • Neurological and vascular damage • Temporary hypoesthesia of the mental nerve • Paresthesia • Loosening of implants • Mesh exposure (*specified only for meshes)* • Membrane exposure / perforation • Incorrect graft selection • Graft loss (e.g. bone block) / failure / resorption (total or partial) • Continuous bone resorption (stress shielding)
Intended patient population	Adult patients who are able to follow the surgeon's instructions regarding aftercare
Intended user group	Oral surgeons Maxillofacial surgeons

3. Product description

Our implants are used in dental implantology for the augmentation / reconstruction of jawbone (including alveolar ridge defects). This involves restoring lost bone substance in the upper or lower jaw, with the goal of building up the bone so that the future dental implant is surrounded on all sides by bone with a thickness of at least 1 mm. Causes of lost bone substance include, among others:

- Tooth loss and lack of natural stress (bone atrophy)
- Periodontitis
- Trauma or pathological processes (e.g. cysts)

Adequate bone volume is essential for the placement of dental implants. In the field of augmentation, there are different techniques that are used depending on the case and/or training or preferences of the doctor. These include, for example: the bone block method (e.g. onlay technique), shell technique (*syn.: bone shell technique*), the tenting technique (*syn.: tent or tentpole or umbrella technique*) and the titanium mesh technique. These techniques all have one thing in common: they usually require bone substitute materials (KEM) with which defects are filled and which are supposed to (re)vascularize or (re)vitalize themselves by attaching themselves to the still existing bone. This is a prerequisite not only for the subsequent dental implant to be successfully placed, but also for it to achieve an acceptable survival rate. For this process to take place, the bone graft material must be applied, shaped, and secured at the desired site and to the desired extent, and the augmented area must also be protected.

This is where our implants come into play. They serve as tools help meet these basic requirements. There are many augmentation techniques, and each places different demands on these tools. Furthermore, when selecting both the technique and the tools, the surgeon must evaluate each individual case.

A term often used in connection with these techniques is "Guided Bone Generation" (GBR). Ultimately, this is a principle that involves targeted bone regeneration by separating the soft tissue from the bone regeneration site using membranes. The goal is to prevent rapidly growing soft tissue from invading the bone defect, allowing new bone to form undisturbed. The risk of soft tissue invasion is significantly higher with particulate augmentation material than with a solid bone block. For smaller defects, it is even possible for new bone to regenerate on its own without the use of augmentation material.

For some of these augmentation techniques and the various requirements associated with them, we provide implants, which are described in more detail in the following chapters.

3.1 Microscrews

Cortical screws

All screws in the screw families described below are designed as cortical to ensure optimal fixation in dense cortical bone. Cortical screws feature a **fine**, **tight thread** to ensure maximum primary stability and reduce the risk of screw pullout.

The relatively **small thread diameters** are also characteristic of a cortical screw. Because the cortical bone has a dense structure, screws must be thinner to prevent excessive stress on the bone or fractures.

All screws are **self-tapping** and non-self-drilling (pre-drilling is required). As a result, they bite into the cortical bone as they are driven in, creating a force-fit connection and thus providing additional stability.

Note: Steel screws used in the shell technique are not always fixed in the cortical bone. In the bilateral shell technique, only two thin bone plates are connected to each other. However, this does not ultimately change the fact that they are designed as cortical screws, since the properties of a cortical screw are particularly required in the unilateral shell technique.

Quadro drive

All our screws are equipped with a Quadro drive. The dev-os Microscrews described below in chapter 3.1.1 have always been equiped with this drive. Given that we have consistently had positive experiences with this drive mechanism to date, there was no reason to choose a different drive mechanism for the dev-os Microscrews / INOX (chapter 3.1.2) and the dev-os Tenting-Screws / INOX (chapter 3.1.3). Furthermore, the drive is considered state-of-the-art according to ASTM F543. The dimensions for the aforementioned square drive connection are well-known and standardized.

3.1.1 dev-os Microscrews / Titanium

<table>
<tr>
<td rowspan="4">Technical description</td>
<td>
DEV-OS | MIKROSCHRAUBEN / TITAN | Ø 1.0
DEV-OS | MICRO SCREWS / TITAN | Ø 1.0
DEV-OS | MICRO-VIS / TITANE | Ø 1.0
QUADRO
5 St. / Packung
5 pcs. / pack
5 pcs. / paquet


<table>
<tr><th>Length:</th><th>5 mm</th><th>7 mm</th><th>9 mm</th><th>11 mm</th><th>13 mm</th><th>15 mm</th></tr>
<tr><td>Ø 1.0 mm</td><td>4010-05</td><td>4010-07</td><td>4010-09</td><td>-</td><td>-</td><td>-</td></tr>
</table>
</td>
<td>Other specifications:
Thread pitch: 0.4 mm;
Head Ø: 1.8 mm;
Head Height: 0.7mm;
Outer Ø Weight: 1.0 mm;
Core Ø: 0.65 mm
Material: Ti6Al4V</td>
</tr>
<tr>
<td>
DEV-OS | MIKROSCHRAUBEN / TITAN | Ø 1.3
DEV-OS | MICRO SCREWS / TITAN | Ø 1.3
DEV-OS | MICRO-VIS / TITANE | Ø 1.3
QUADRO
5 St. / Packung
5 pcs. / pack
5 pcs. / paquet


<table>
<tr><th>Length:</th><th>5 mm</th><th>7 mm</th><th>9 mm</th><th>11 mm</th><th>13 mm</th><th>15 mm</th></tr>
<tr><td>Ø 1.3 mm</td><td>4013-05</td><td>4013-07</td><td>4013-09</td><td>4013-11</td><td>4013-13</td><td>4013-15</td></tr>
</table>
</td>
<td>Other specifications:
Thread pitch: 0.6 mm;
Head Ø: 2.5 mm;
Head height: 1.11 mm;
Outer Ø weight: 1.3 mm;
Core Ø: 0.8 mm
Material: Ti6Al4V</td>
</tr>
<tr>
<td>
DEV-OS | MIKROSCHRAUBEN / TITAN | Ø 1.5
DEV-OS | MICRO SCREWS / TITAN | Ø 1.5
DEV-OS | MICRO-VIS / TITANE | Ø 1.5
QUADRO
5 St. / Packung
5 pcs. / pack
5 pcs. / paquet


<table>
<tr><th>Length:</th><th>5 mm</th><th>7 mm</th><th>9 mm</th><th>11 mm</th><th>13 mm</th><th>15 mm</th></tr>
<tr><td>Ø 1.5 mm</td><td>4015-05</td><td>4015-07</td><td>4015-09</td><td>4015-11</td><td>4015-13</td><td>4015-15</td></tr>
</table>
</td>
<td>Other specifications:
Thread pitch: 0.6 mm;
Head Ø: 2.5 mm;
Head height: 1.0mm;
Outer Ø weight: 1.5 mm;
Core Ø: 1.0 mm
Material: Ti6Al4V</td>
</tr>
<tr>
<td>
DEV-OS | MIKROSCHRAUBEN / TITAN | Ø 1.8
DEV-OS | MICRO SCREWS / TITAN | Ø 1.8
DEV-OS | MICRO-VIS / TITANE | Ø 1.8
QUADRO
5 St. / Packung
5 pcs. / pack
5 pcs. / paquet


<table>
<tr><th>Length:</th><th>5 mm</th><th>7 mm</th><th>9 mm</th><th>11 mm</th><th>13 mm</th><th>15 mm</th></tr>
<tr><td>Ø 1.8 mm</td><td>4018-05</td><td>4018-07</td><td>4018-09</td><td>4018-11</td><td>4018-13</td><td>4018-15</td></tr>
</table>
</td>
<td>Other specifications:
Thread pitch: 0.6 mm;
Head Ø: 2.5 mm;
Head height: 0.92 mm;
Outer Ø weight: 1.8 mm;
Core Ø: 1.3 mm
Material: Ti6Al4V</td>
</tr>
<tr>
<td>Application Description:</td>
<td colspan="2">Our dev-os Microscrews / Titanium are usually used as lag screws in the context of jawbone augmentations in the so-called onlay technique. A solid bone block, often taken from the retromolar area of the lower jaw or the iliac crest, is inserted into the defect and secured with titanium screws. The screws have the task of keeping the bone block stable in place over the duration of the augmentation period and establishing a firm connection to the still existing healthy bone so that a build-through (vascularization / vitalization) can take place. It is important to pre-drill the drill hole in the bone block larger than in the</td>
</tr>
</table>

original bone. This creates interfragmentary compression to enable the firm connection that is so important for this technique. The large screw head further reinforces this.

This technique allows for both vertical and horizontal augmentation. Although other augmentation techniques, such as the shell technique acc. to Khoury or the tenting technique, are gaining popularity, the onlay technique is still widely used because it is relatively simple to perform.

These screws are made of grade 5 titanium (Ti6Al4V). A decisive disadvantage of titanium is that the material is much softer and therefore less stable. Especially when connecting long screws with thin diameters, micro screws made of titanium reach their limits. Perhaps the most characteristic property of titanium is its ability to osseointegrate, i.e. to fuse with the bone. However, since our screws are not intended to remain permanently in the body, this can also be a disadvantage when it comes to removing the screws.

The great advantage of titanium is its greater biological compatibility with steel. Stainless steel screws are more likely to trigger foreign body reactions, which is why titanium screws are particularly in demand when patients with material intolerances to implant steel are to be treated. Therefore, they must be available as an important alternative.

As shown above, the user has a wide range of diameter-length combinations at their disposal, and must evaluate which one to choose based on the specific case. In doing so, he must always keep in mind that on the one hand he chooses the thinnest possible diameters in order to proceed as minimally invasive as possible, but on the other hand he must also take into account the required stability. The length of the screw to be used is closely related to the size of the bone defect and, consequently, the size of the bone block. The responsibility for the correct choice lies with the user (surgeon, implantologist). The larger screw diameters of 1.5 and 1.8 mm are mostly used as emergency screws.

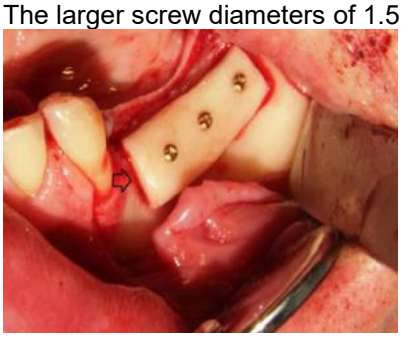
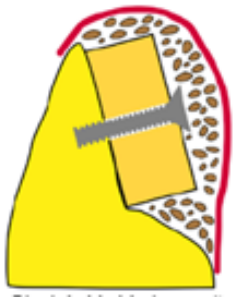


Figure 1: The bone graft is inserted into the bone defect in the left maxillary posterior region and fastened with three titanium microscrews (see arrow).

Functionality / Application principle:	The screws are used as lag screws and are capable of creating a secure connection between the graft and the original bone, maintaining this connection throughout the entire healing period. This is further supported by the design of the screw head. Since they have a fine, narrow thread, they are ideal for fixation in the cortical bone.  Figure 2: Block in connection with lag screws
Previous generations / variants	Our dev-os Microscrews / Titanium have not been changed since they were first placed on the market (01.09.2020). Consequently, there are neither previous generations nor variants.

3.1.2 dev-os Microscrews / INOX

<table>
<tr>
<td rowspan="2">Technical description</td>
<td>
DEV-OS | MIKROSCHRAUBEN / INOX | Ø 1.0
DEV-OS | MICRO SCREWS / INOX | Ø 1.0
DEV-OS | MICRO-VIS / INOX | Ø 1.0

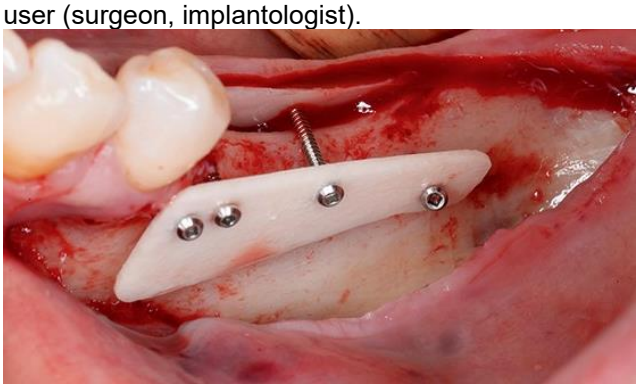

<table>
<tr><td>Length</td><td>4 mm</td><td>6 mm</td><td>8 mm</td><td>10 mm</td><td>12 mm</td><td>14 mm</td></tr>
<tr><td>Ø 1.0 mm</td><td>4510-04</td><td>4510-06</td><td>4510-08</td><td>4510-10</td><td>4510-12</td><td>4510-14</td></tr>
</table>
</td>
<td>Other specifications:
Thread pitch: 0.425 mm;
Head Ø: 1.72 mm;
Head height: 0.84mm;
Outer Ø Weight: 1.0 mm;
Core Ø: 0.63 mm
Material: Implant steel 1.4441</td>
</tr>
<tr>
<td>
DEV-OS | MIKROSCHRAUBEN / INOX | Ø 1.2
DEV-OS | MICRO SCREWS / INOX | Ø 1.2
DEV-OS | MICRO-VIS / INOX | Ø 1.2

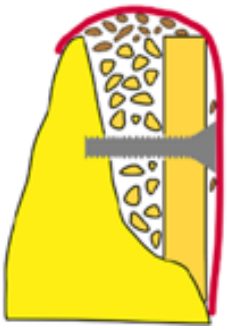

<table>
<tr><td>Length</td><td>4 mm</td><td>6 mm</td><td>8 mm</td><td>10 mm</td><td>12 mm</td><td>14 mm</td></tr>
<tr><td>Ø 1.2 mm</td><td>4512-04</td><td>4512-06</td><td>4512-08</td><td>4512-10</td><td>4512-12</td><td>4512-14</td></tr>
</table>
</td>
<td>Other specifications:
Thread pitch: 0.47 mm; Head Ø: 1.72 mm;
Head Height: 0.75mm;
Outer Ø Weight: 1.2 mm;
Core Ø: 0.73 mm
Material: Implant steel 1.4441</td>
</tr>
<tr>
<td>Application Description:</td>
<td colspan="2">Our dev-os Microscrews / INOX (made of implant steel) are usually used as adjusting screws in the context of jawbone augmentations in the so-called shell technique. The shell technique according to Khoury is an advanced method for the reconstruction of bone defects in implantology. It is based on the use of thin bone shells (1-2 mm) made mostly from autologous or allogeneic bone, which, when secured with microscrews, serve as a kind of "container" for particulate bone material.

Our screws have the task of stabilizing the bone shells and holding them in place for the entire duration of the augmentation. This creates a defined augmentation chamber and ensures that optimal bone regeneration can take place through fixation and protection of the augmented area from micro-movements.

The technique enables stable augmentation, especially for vertical and horizontal defects, and can be used quite flexibly. By using particulate bone and/or bone substitute material, it offers the great advantage over the onlay technique that the augmentation material can be built through better. However, particulate bone has to be protected more elaborately, which in turn makes this technique more technically challenging.

Our dev-os Microscrews / INOX are made of implant steel (1.4441). The main advantage of stainless steel compared to titanium is its greater stability. Especially with the shell technique, it can happen that long thin screws are needed to connect</td>
</tr>
</table>

	bone shells placed palatal and vestibularly with each other. Another advantage of stainless steel is that it does not osseointegrate, making it easier to remove the screws after the healing phase The disadvantage of steel screws is their lower biological compatibility compared to titanium, which is why users like to use titanium screws, especially for patients with a material intolerance to metal. When designing the screw heads, care was taken to keep the head diameter rather small in order to protect the fine bone shells, which react sensitively to punctual loads. A screw head that is too large could put the material under tension and cause fine fractures. The smaller head geometry reduces the pressure load, so that the bone structure is less affected. The head height has also been reduced as much as possible to reduce the likelihood of screw exposure. As can be seen above, the user has a large selection of diameter-length combinations at his disposal, the selection of which he has to evaluate depending on the case. In doing so, he must always keep in mind that on the one hand he chooses the thinnest possible diameters in order to proceed as minimally invasive as possible, but on the other hand he must also take into account the required stability. The length of the screw to be used is closely related to the size of the bone defect and, consequently, the augmentation plan and goal. The responsibility for the correct choice lies with the user (surgeon, implantologist).  Figure 3: Augmentation in the 3rd quadrant with two allogeneic bone plates and autologous bone chips in the shell technique.  Figure 4: Application of the allogeneic shell technique with one shell for horizontal and vertical augmentation with simultaneous implantation.
Functionality / Application principle:	The screws enable secure fixation and stabilization of thin bone shells on the original bone. They are used as adjusting screws and hold the bone shells in place for the entire duration of the augmentation. In this way, they help to ensure that the augmentation height is determined by the defined boundary and that the particulate augmentation material introduced in the "biological container" created by the bone shells (usually in conjunction with membranes) can be protected from soft tissue

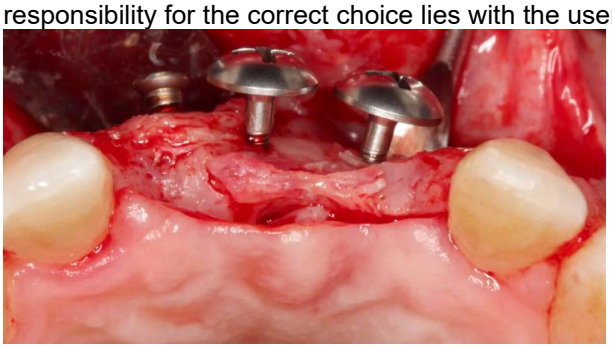
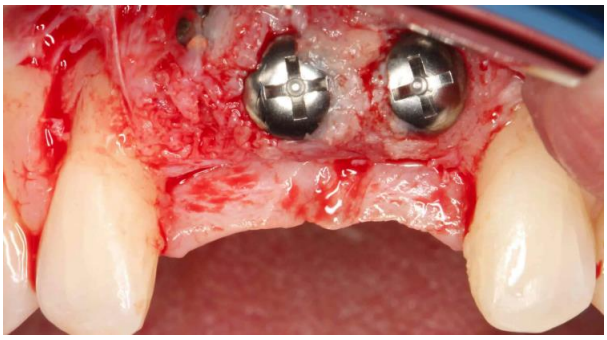
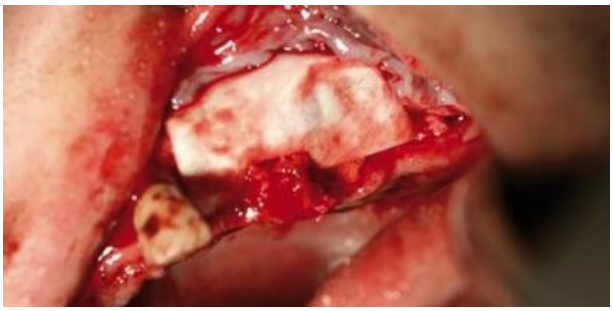
	ingrowth. This ensures that optimal bone regeneration can take place through fixation and protection of the augmented area from micro-movements.  Figure 5: Block in connection with position screws
Previous generations / variants	None, as first registration according to MDR

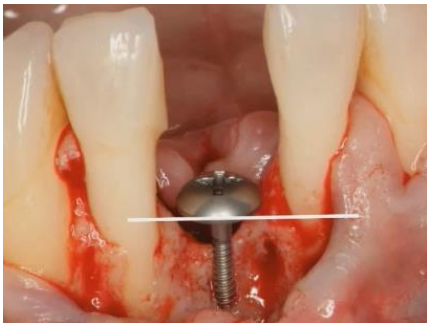
3.1.3 dev-os Tenting-Screws / Titanium

Technical description	DEV-OS | TENTING-SCREWS / INOX (EDELSTAHL) DEV-OS | TENTING-SCREWS / INOX (STAINLESS STEEL) DEV-OS | TENTING-SCREWS / INOX (ACIER INOXYDABLE) 	Other specifications: Thread pitch: 0.45 mm; Outer Ø Weight: 1.2 mm; Core Ø: 0.8 mm Material: Implant steel (1.4441)

Length:	8 mm	10 mm	12 mm	8 mm	10 mm	12 mm
Head:	Ø 4.0 mm	Ø 4.0 mm	Ø 4.0 mm	Ø 6.0 mm	Ø 6.0 mm	Ø 6.0 mm
Ø 1.2 mm	4712-04-08	4712-04-10	4712-04-12	4712-06-08	4712-06-10	4712-06-12

Application Description:	Our dev-os Tenting-Screws / INOX (made of implant steel) are usually used as adjusting screws in the context of jawbone augmentations in the so-called tenting technique. This technique, as with all techniques that use the principle of GBR, is ultimately about creating volume, space and rest for the particulate augmentation material and thus being able to build up or regenerate bone safely and reliably. The Tenting-Screws are screwed into the original bone in such a way that they stand like an "umbrella" over the augmentation area and take on a barrier function. The space created under the “umbrella” is then filled with particulate bone material. This results in the need for different screw lengths: The lower edge of the screw head specifies the defined augmentation height. The tenting technique was originally performed with small mini osteosynthesis screws with small screw heads. These had the decisive disadvantage that they could create less space and more often perforated membranes that were placed over the augmented area to protect it. The technique enables stable augmentation. In principle, it can be used for both horizontal and vertical defects, although vertical augmentations are technically much more challenging. The main advantage of this technique is that no suitable bone blocks or shells or titanium grids have to be removed or prepared, and the technique requires less planning. Our dev-os Tenting-Screws / INOX are made of implant steel (1.4441). The main advantage of stainless steel compared to titanium is its greater stability and that it

	does not osseointegrate. This makes it easier to remove the screws after the healing phase. The disadvantage of steel screws is their lower biological compatibility compared to titanium, which is why users like to use titanium screws, especially for patients with a material intolerance to metal. As can be seen above, the user has a large selection of diameter-length combinations at his disposal, the selection of which he has to evaluate depending on the case. The choice of head size, as well as the length of the screw to be used, is closely related to the size of the bone defect and, consequently, the augmentation plan and goal. The responsibility for the correct choice lies with the user (surgeon, implantologist).  Figure 6: Augmentation in the anterior region; Tenting-Screws are not completely screwed into the bone.  Figure 7: Intentional distance from bone to lower edge of screw head filled with bone substitute material.  Figure 8: Closure of the surgical field by means of membrane
Functionality / Application principle:	The screws enable secure fixation in the original bone. They are screwed into the bone as adjusting screws only so deep that the underside of the screw head defines the augmentation height. They are able to hold the particulate bone material inserted under the umbrella-shaped screw head in place for the entire duration of the augmentation. They also create and maintain a distance between soft tissue and augmentate (usually in conjunction with membranes), which prevents soft tissue from ingrowing. This ensures that optimal bone regeneration can take place through fixation and protection of the augmented area from micro-movements.

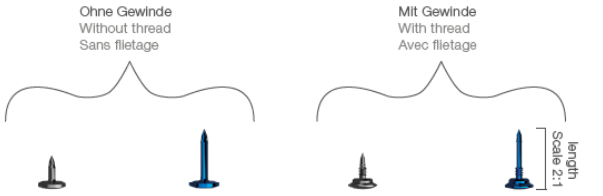
	 Figure 9: Tenting technique with Tenting-Screws
Previous generations / variants	None, as first registration according to MDR

3.2 dev-os Titanium Pins / Solid-Pins

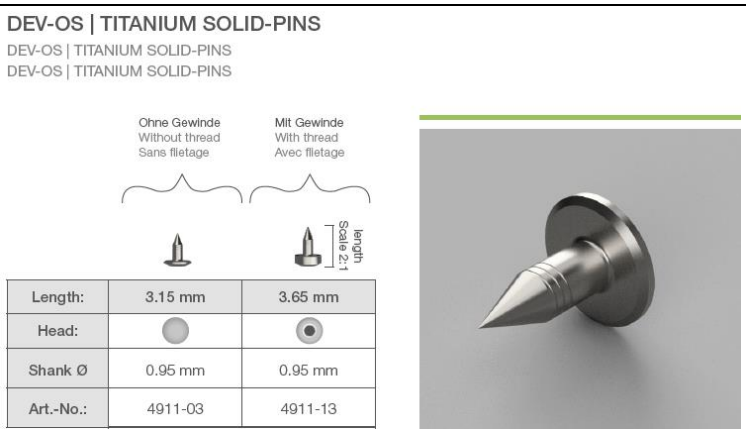
Titanium pins play an important role in Guided Bone Regeneration (GBR). Guided bone regeneration is less about repairing the damaged jawbone and more about regeneration. The body is supported in rebuilding bone substance on its own. For this purpose, a protective membrane is placed under the mucous membrane and over the jawbone during a short procedure to provide a protective framework for newly developing bone. The bone thus has the chance to heal and rebuild itself.

However, the term GBR is also used when bone grafting materials are employed in addition, such as in the shell, tenting, or titanium mesh techniques. This is especially the case with higher bone loss, when the larger cavity under the membrane is filled at the same time with, for example, bone grafting materials. On the one hand, this ensures the stability of the membrane and, on the other hand, prevents soft tissue from occupying the cavity and new bone material from having no place in the long term - because soft tissue grows faster than bone.

Membranes are available in a number of variants, shapes and materials. These include our titanium meshes, which are therefore sometimes referred to as titanium mesh membranes. Our titanium pins are used to fix membranes and meshes to the bone.

Technical description	DEV-OS | TITANIUM PINS DEV-OS | TITANIUM PINS DEV-OS | TITANIUM PINS 	Material: Titanium Grade 5 (Ti6Al4V)

Length:	3 mm	5 mm	3 mm	5 mm
Head:				
Shank Ø	0.6 mm	0.6 mm	0.54	0.54
Art.-No.:	4901-03	4901-05	4901-13	4901-15



Application Description:

Our dev-os Titanium Pins are “punshed” into the bone as part of GBR techniques for the fixation of membranes and titanium meshes, which serve as a barrier between bone and soft tissue. Their task is to keep these barriers in place for the duration of the augmentation or regeneration period.
Our dev-os Titanium Pins are made of grade 5 titanium (Ti6Al4V). Due to the high biocompatibility of the material and its corrosion resistance, the risk of inflammation or infection is reduced. All pins have a head diameter of 2.5 mm. They can therefore all be inserted with the same application instruments (see combination products). This head size is sufficient to be able to fix membranes and meshes.

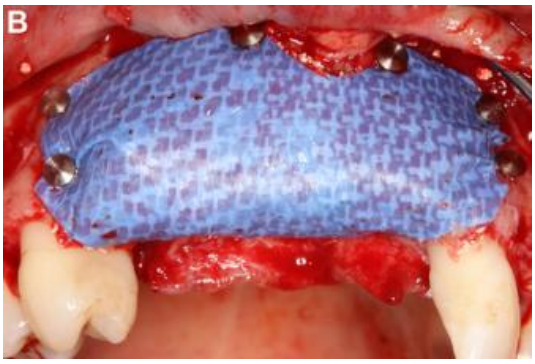
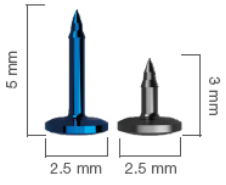


Figure 10: Membrane fixation with titanium pins in the maxillary anterior region

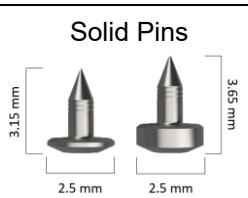
Our standard threadless pins are available in total lengths of 3 mm (#4901-03) and 5 mm (#4901-05). With the same head height (0.6 mm), this has different effects on the impact depth (2.4 and 4.4 mm). The relatively flat head also helps to reduce the risk of soft tissue perforations. Both pins have a shaft diameter of 0.6 mm and feature a barb near the tip that prevents the pins from detaching from the bone on their own. The longer pin is anodized blue for better identification.

Pins without thread



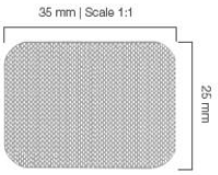
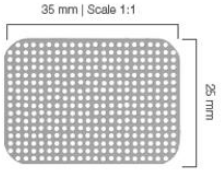
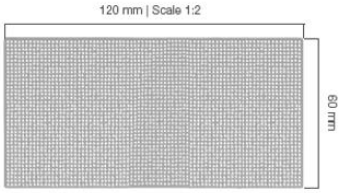
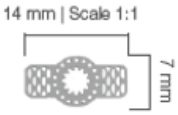
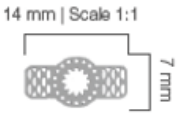
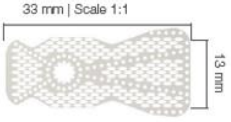
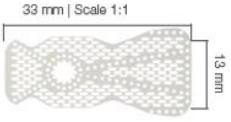
Our standard threaded pins (HEX HEAD) are available in total lengths of 3 mm (#4901-13) and 5 mm (#4901-15). The head is slightly higher at 0.91mm compared to the unthreaded pins. The reason for this is the drive, which requires a little more depth. In combination with the thread, which is relatively close to the head and does not reach the tip to the front, this contributes to easier removal of the pins. Both pins have a shaft diameter of 0.54 mm and feature a kind of barb near the tip that prevents the pins from detaching from the bone on their own. The longer pin is anodized blue for better identification.

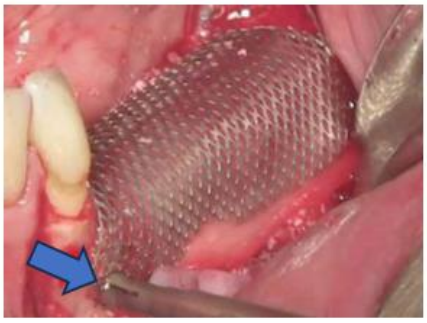
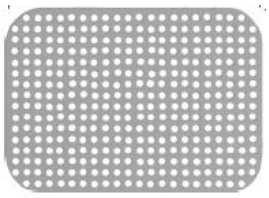
Threaded pins

	Our solid pins are also available in a variant without thread (#4911-03) and with thread (4911-13), each with an impact depth of 2.65 mm and a shaft diameter of 0.95 mm. The difference in total length results from the different head heights. While one pin has a particularly flat head design (head height 0.5 mm) and is therefore ideal for use under thin soft tissue, for example, the other pin has a larger head design (head height: 1.0 mm) due to the drive, which also makes it easier to find the pins under the soft tissue after successful healing. With their sharp tip, they can be easily and precisely inserted into the cortical bone. Due to the significantly thicker shaft (0.95 mm) compared to the standard pins, they are particularly suitable for hard bones.	
Functionality / Application principle:	Titanium pins allow membranes to be fixed in the cortical jawbone during GBR. In this way, they help to keep the membrane stable over the augmentation area, allowing it to act as a barrier against soft tissue and allow for controlled bone regeneration. The functional principle is similar to that of a rice nail: The titanium pin is punshed through the membrane into the cortical bone surface. Due to its shape (sharp tip with barb/retaining groove), it anchors itself firmly in the bone and keeps the membrane tension-free and motionless in place.  Figure 11: Fixing a membrane with a pin	
Previous generations / variants	dev-os Titanium Pin: Our dev-os Titanium Pins have not been modified since they were first placed on the market (01.09.2020). Consequently, there are neither previous generations nor variants. dev-os Titanium Solid-Pins: None, because first approval according to MDR	

3.3 dev-os Titanium Micro-Meshes / Tenting-Meshes

Titanium meshes play an important role in augmentation using the principle of Guided Bone Regeneration (GBR) in conjunction with bone grafting materials. Depending on the intended use, they have several tasks: to form a biological container, to hold the bone filling material in the desired place and to protect it. The meshes are secured to the bone using pins or screws.

Technical description	DEV-OS | TITANIUM MICRO MESHES DEV-OS | TITANIUM MICRO MESHES DEV-OS | TITANIUM MICRO MESHES **4904-12** 0.1 mm | Perf.: oval, fein | 34 x 25 mm 0.1 mm | Perf.: oval, fine | 34 x 25 mm 0.1 mm | Perf.: ovale, fin | 34 x 25 mm  **4904-13** 0.1 mm | Perf.: rund | 34 x 25 mm 0.1 mm | Perf.: round | 34 x 25 mm 0.1 mm | Perf.: rond | 34 x 25 mm  **4904-15** 0.1 mm | Perf.: rund | 120 x 60 mm 0.1 mm | Perf.: round | 120 x 60 mm 0.1 mm | Perf.: rond | 120 x 60 mm  **DEV-OS | TITANIUM TENTING MESHES** DEV-OS | TITANIUM TENTING MESHES DEV-OS | TITANIUM TENTING MESHES **4904-30** 0.2 mm | Öffnung Ø 3.1 mm | 7 x 14 mm 0.2 mm | Opening Ø 3.1 mm | 7 x 14 mm 0.2 mm | Ouverture Ø 3.1 mm | 7 x 14 mm  **4904-31** 0.2 mm | Öffnung Ø 3.6 mm | 7 x 14 mm 0.2 mm | Opening Ø 3.6 mm | 7 x 14 mm 0.2 mm | Ouverture Ø 3.6 mm | 7 x 14 mm  **4904-40** 0.2 mm | Öffnung Ø 3.1 mm | 13 x 33 mm 0.2 mm | Opening Ø 3.1 mm | 13 x 33 mm 0.2 mm | Ouverture Ø 3.1 mm | 13 x 33 mm  **4904-41** 0.2 mm | Öffnung Ø 3.6 mm | 13 x 33 mm 0.2 mm | Opening Ø 3.6 mm | 13 x 33 mm 0.2 mm | Ouverture Ø 3.6 mm | 13 x 33 mm  	Material: Titanium Grade 2

Application Description:	With our dev-os Titanium Meshes, GBR techniques can be performed in conjunction with meshes for jawbone augmentation and/or repair of alveolar bone defects. They serve as a dimensionally stable barrier to keep bone grafting material or autologous bone in the desired shape, while at the same time keeping soft tissue away and specifically supporting new bone formation. There are essentially three surgical methods when it comes to use: 1) Simultaneous implantation with bone augmentation with titanium mesh 2) delayed implantation with bone augmentation with titanium mesh 3) Combination of titanium mesh with other bone augmentation techniques in GBR Titanium meshes are available either a) pre-cut and pre-bent or b) pre-cut or c) unprepared. The latter variant has the advantage that they can be used flexibly. This means that the user can cut the shape to the desired size and adapt / model the mesh to the defect. The use therefore requires less lead time and planning compared to pre-formed 3D meshes. The disadvantage, however, is that the meshes may have to be deburred and bent after cutting. Variant b) includes our tenting meshes. These no longer have to be cut by the user. They are inserted in single-stage implantation procedures and secured by the cover screw of the denture implant. Our dev-os Titanium Meshes are made of grade 2 titanium. Due to the high biocompatibility of the material and its corrosion resistance, the risk of inflammation or infection is reduced.
	dev-os Titanium-Micro-Meshes: Our dev-os Titanium Micro-Meshes belong to variant c) described above and are suitable for methods 2+3 (two-stage implantation procedures). They must therefore be cut to size by the user (with crown scissors, see combination products) and the resulting sharp cut edges must be smoothed out by folding / bending (with flat-nose pliers, see combination products). Subsequently, manual modeling is carried out on a 3D model before the now preformed mesh can or must be sterilized. To make all this possible, these meshes have a thickness of just 0.1 mm. They differ only in the outer dimensions and the mesh width (0.1 mm round or fine, oval). The structure of the augmentation usually determines the choice of mesh width.  Figure 12: Fixation of a titanium mesh cut by the user and modeled on the jawbone during a two-stage implantation procedure
	

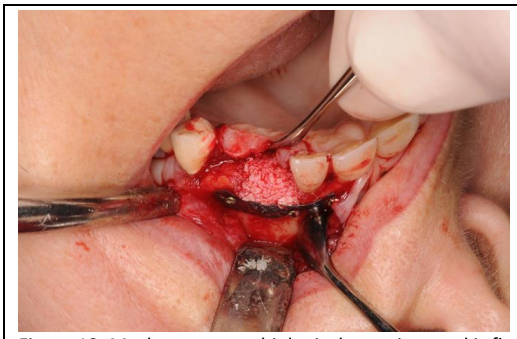
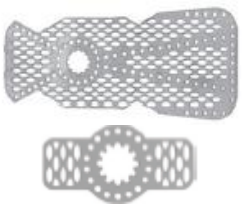


Figure 13: Mesh serves as a biological container and is fixed to the jawbone with microscrews at a defined distance

dev-os Titanium Tenting Meshes

Our dev-os Titanium Tenting meshes belong to variant b) described above and are suitable for method 1 (single-stage implantation procedure). This means that they no longer have to be cut to size by the user, but only bent. Characteristic of meshes for two-stage procedures is the round recess that can be placed around the shaft of the implant. The meshes all have a thickness of 0.2 mm, which allows for relatively easy modeling without the risk of kinking. They differ only in the shape/external dimensions and the size of the opening.

Figure 14: Mesh fixation in single-stage implantation procedure. Augmentation takes place immediately after implantation of the dentures in the same procedure.



Functionality / Application principle:	A mesh is to be understood as a kind of cage that a) specifies the contour of the area to be augmented b) "locks in" the augmentation material, holds it in place and ensures a mechanically stable environment c) has a barrier function between soft tissue and the bony regeneration area.
Previous generations / variants	dev-os Titanium Micro-Meshes: Since 01.09.2020, devemed has been the manufacturer for this product group. At the time of the MDD approval at that time, the following variants were in the program:  These will be removed from the program for strategic reasons in the course of admission according to MDR and replaced by the variants described above.

	30 x 40 mm	40 x 60 mm
0,1 mm	4904-10	4904-11
0,2 mm	4904-20	

	dev-os Titanium Tenting-Meshes: None, because first approval according to MDR

3.4 Combination Products & Accessories

General Accessories

The following storage boxes are available for the components (screws, pins & instruments). These are not only used for storage, but also for easier storage of screws and pins:

#4400-10 — dev-os Toolbox

The Toolbox features a clear layout that makes it easy to locate items and find your way around. It can be individually equipped and has recesses for the handle, screws, pins, various drills, screwdriver blades, pin applicator and pin turner.

It allows for easy picking up of screws and pins.

#4400-15 — dev-os Cube

The Cube can be used for all implants due to its modular design It allows for easy picking up of screws and pins.

#4903-00 FBC - Pin Box; Stainless steel with DLC black-coating

The Pin Box made of stainless steel with the DLC black-coating can be easily opened with one hand and offers space for 15 pins. The coating prevents the titanium from scratching, as it acts as a barrier between the titanium and the stainless steel. In addition, the black finish enhances the contrast with the pins, making them more visible.

dev-os Microscrews / Titanium

Accessories include pilot drills for pre-drilling, insertion instruments (blades, screwdriver handle) and storage boxes.

Pilot Drill

# 4210-00	Pilot drill Ø 0.7 for Microscrews 4010-XX
# 4213-00	Pilot drill Ø 1.0 for Microscrews 4013-XX
# 4215-00	Pilot drill Ø 1.2 for Microscrews 4015-XX
# 4218-00	Pilot drill Ø 1.5 for Microscrews 4018-XX

For the application of the dev-os Microscrews / Titanium, a pre-drilling in the recipient bone must be carried by using a drill that is 0.3 mm smaller in diameter. To ensure a secure connection, the bone block should be pre-drilled with a hole that is at least as large as the diameter of the screw's external thread. In addition, the drilling depth must be determined in order to select the appropriate screw length. The choice of the drill depends on the choice of the screw (specifications described in detail in IFU).

The drills can only be operated with dental drive units (active medical devices of class IIa) that allow the use of type 1 shanks in accordance with DIN EN ISO 1797 (contra-angle handpiece) and comply with the requirements of EN ISO 14457.

 # 4311-00 - Screwdriver handle

Hand-operated rotary handle suitable for screwdriver blades for simplified tightening and loosening of screws.

 # 4902-50 - Pin-Driver

Handle suitable for screwdriver blades for manually tightening and loosening screws (recommended in hard-to-reach areas).

Screwdriver blades

For screw system 1.0

# 4210-20	with a total length of 70 mm; green color marking
# 4210-21	with a total length of 30 mm; green color marking

		For screw system 1.3 / 1.5 / 1.8
	# 4213-20	in total length 70 mm; black color marking
	# 4213-21	in total length 30 mm; black color marking

The shorter screwdriver blades (30 mm) are recommended for insertions in hard-to-reach areas (e.g. palatal or buccal inserts) in conjunction with our Pin Driver. To do this, the blade can be easily replaced and the lathe can be operated manually.
For the insertion of screws in easily accessible areas (e.g. anterior tooth area), we recommend the use of the longer screwdriver blades (70 mm) in conjunction with the screwdriver handle (#4311-00). Ultimately, the choice is up to the user.

The combination of the screws with products from other manufacturers is prohibited in the IFU, as the components used may not be coordinated with each other and could negatively influence the result of the procedure.

This does not apply to the combination with bone grafting materials such as e.g. allogeneic bone shells or autogenous particulate bone grafting materials. In this regard, the IFU points out the following:
"*The microscrews can be combined with the products listed in the AWMF guideline "Implantological indications for the use of bone substitute materials" (register no.: 083-009)."*

dev-os Microscrews / INOX

Accessories include pilot drills for pre-drilling, insertion instruments (blades, screwdriver handle) and storage boxes.

	**Pilot Drill**	
	# 4210-10 / -14	Pilot Drill Ø 0.8 mm for Microscrews 4510-XX
	# 4212-10 / -14	Pilot Drill Ø 1.0 mm for Microscrews 4512-XX

For the application of the dev-os Microscrews / INOX for shell technology, a pre-drilling in the recipient bone and bone graft must be carried out by using a drill with a diameter of 0.2 mm. In addition, the drilling depth for the selection of the appropriate screw length must be determined. The choice of the drill depends on the choice of the screw and augmentation region. For use in the buccal area, we recommend the shorter drill (specifications precisely described in IFU).

The drills can only be operated with dental drive units (active medical devices of class IIa) that allow the use of type 1 shanks in accordance with DIN EN ISO 1797 (contra-angle handpiece) and comply with the requirements of EN ISO 14457.

	**# 4311-00 - Screwdriver handle** Hand-operated rotary handle suitable for screwdriver blades for simplified tightening and loosening of screws.
	**# 4902-50 - Pin-Driver** Handle suitable for screwdriver blades for manually tightening and loosening screws (recommended in hard-to-reach areas).
	**Screwdriver Blades**

# 4210-30	Total length 70 mm; blue-white colour marking
# 4210-31	Total length 30 mm; blue-white colour marking

The shorter screwdriver blade (30 mm) is recommended for insertions in hard-to-reach areas (e.g. palatal or buccal inserts) in conjunction with our Pin Driver. To do this, the blade can be easily replaced and the lathe can be operated manually.
For the insertion of screws in easily accessible areas (e.g. anterior tooth area), we recommend using the longer screwdriver blade (70 mm) in conjunction with the screwdriver handle (#4311-00). Ultimately, the choice is up to the user.

The combination of the screws with products from other manufacturers is prohibited in the IFU, as the components used may not be coordinated with each other and could negatively influence the result of the procedure.

This does not apply to the combination with bone substitute materials such as e.g. allogeneic bone shells or autogenous particulate bone grafting materials. In this regard, the IFU points out the following:
"*The microscrews can be combined with the products listed in the AWMF guideline "Implantological indications for the use of bone substitute materials" (register no.: 083-009)."*

dev-os Tenting-Screws / INOX

Accessories include pilot drills for pre-drilling, insertion instruments (blades, screwdriver handle) and storage boxes.

Pilot Drill

# 4212-08	Pilot drill Ø 1.0 mm for Tenting-Screws 4712-XX-XX

For the application of the dev-os Tenting-Screws / INOX, a pre-drilling hole must be carried out in the recipient bone by using a drill with a diameter of 0.2 mm. In addition, the drilling depth for the selection of the appropriate screw length must be determined. (Specifications described in detail in IFU).

The drills can only be operated with dental drive units (active medical devices of class IIa) that allow the use of type 1 shanks in accordance with DIN EN ISO 1797 (contra-angle handpiece) and comply with the requirements of EN ISO 14457.

 # 4311-00 - Screwdriver handle

Hand-operated rotary handle suitable for screwdriver blades for simplified tightening and loosening of screws.

 # 4902-50 - Pin-Driver

Handle suitable for screwdriver blades for manually tightening and loosening screws (recommended in hard-to-reach areas).

Screwdriver Blades

# 4213-30	Total length 70 mm; red colour marking
# 4213-31	Total length 30 mm; red colour marking

The shorter screwdriver blade (30 mm) is recommended for insertions in hard-to-reach areas (e.g. palatal or buccal inserts) in conjunction with our Pin Driver. To do this, the blade can be easily replaced and the lathe can be operated manually.
For the insertion of screws in easily accessible areas (e.g. anterior tooth area), we recommend using the longer screwdriver blade (70 mm) in conjunction with the screwdriver handle (#4311-00). Ultimately, the choice is up to the user.

The combination of the screws with products from other manufacturers is prohibited in the IFU, as the components used may not be coordinated with each other and could negatively influence the result of the procedure.

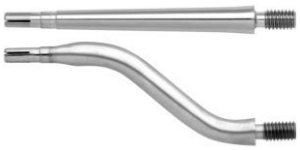
This does not apply to the combination with bone substitute materials such as e.g. allogeneic bone shells or autogenous particulate bone grafting materials. In this regard, the IFU points out the following:
"*The microscrews can be combined with the products listed in the AWMF guideline "Implantological indications for the use of bone substitute materials" (register no.: 083-009)."*

dev-os Titanium Pins

Accessories include a drill for setting bleeding points, insertion instruments (Applicators and Center-Punch) as well as explantation instruments (Pin Removers) and storage boxes.

	**# 4210-08 – Dentaldrill** **The drill can be used to refresh the cortical bone by setting bleeding points.**

Notice:
The drill can only be operated with dental drive units (active medical devices of class IIa) that allow the use of type 1 shanks in accordance with DIN EN ISO 1797 (contra-angle handpiece) and comply with the requirements of EN ISO 14457.

	**# 4902-20 - Pin-Applicator** The applicator facilitates convenient removal of the pins from the boxes and direct application in the jaw.
	**# 4902-55 - Pin-Driver** The Pin-Driver allows the HEX-HEAD pins inserted in the jaw to be quickly and easily removed after healing.
	**# 4311-00 - Screwdriver handle** Hand-held rotary handle suitable for Pin-Applicator (#4902-20) and Pin-Driver (#4902-55)
	**# 4902-00 F - Handle for Pin-Applicators** The pin applicators # 4902-10 / -15 can be screwed into this handle. It provides a good grip during pulling and pushing movements and enables direct force transmission to the pin.
	**Pin-Applicators** **# 4902-10 straight** **# 4902-15 curved** The applicators allow the pins to be conveniently removed from the boxes and attached directly to the jaw.
	**# 4902-50 - Pin-Driver** The Titanium Pin-Driver allows the HEX-HEAD pins attached to the jaw to be quickly and easily removed by hand after healing.
	**# 4902-70 F - Pin-Remover** Pin-Remover for easy removal of the pins from the alveolar ridge after healing.
	**# 4902-80 F - Center Punch for Pins** The very pointed working part can be used to pre-punch holes for pins in bone and membrane.
	**# 860-20 F - Mallet** Mallet for driving pins using handle 4902-00 F for pin applicators.

The combination of the pins with products from other manufacturers is prohibited in the IFU, as the components used may not be coordinated with each other and could negatively influence the result of the procedure.

This does not apply to the combination with bone substitute materials and membranes. In this regard, the IFU points out the following:
"*The microscrews can be combined with the products listed in the AWMF guideline "Implantological indications for the use of bone substitute materials" (register no.: 083-009)."*

dev-os Titanium Meshes

Accessories include scissors for cutting and flat-nose pliers for deburring/folding the cutting edges (*only micro-meshes necessary*) as well as titanium pins and micro screws / titanium.

 # 2610-1 - Crown Scissors "Beebee" | straight
Scissors for cutting the micro-meshes.

 # 3060 - Flat nose pliers
Pliers for folding down and thus smoothing the cut edges of the meshes

Titanium Pins		Titanium Pins | HEX HEAD		Titanium Solid Pins	
4901-05	4901-13	4901-15	4901-05	4901-13	4901-15
					

dev-os Micro Screws / Titanium		
4010-05(Ø1.0 / 5 mm)	4010-05(Ø1.0 / 5 mm)	4010-05(Ø1.0 / 5 mm)
		

The combination of the meshes with products from other manufacturers is prohibited at the IFU, as the components used may not be coordinated with each other and could have a negative impact on the result of the procedure.

This does not apply to the combination with bone substitute materials and membranes. In this regard, the IFU points out the following:
"*The microscrews can be combined with the products listed in the AWMF guideline "Implantological indications for the use of bone substitute materials" (register no.: 083-009)."*

Likewise, in the case of Tenting Meshes, this does not apply to the denture implants. All dental implants can be used here, with whose locking screws the meshes can be secured. In this regard, the IFU points out the following:
"The meshes can be used with all dental implants, with the cover screws that can be used to secure the meshes."

3.5 Description of other products intended for use in combination with the product

Other products, except those listed in chapter 3.4, are not provided.

4. Risks and warnings

Residual risks and known side effects	**dev-os Microschrauben / dev-os Titanium Pins / dev-os Titanium Meshes** Complications are more often caused by the surgical procedure rather than the implant. • Mucosa or tissue reaction • Skin rash • Loosening of the implant due to insufficient, improper attachment • Implant breakage / swallowing of fragments • Possible nerve or blood vessel damage as a result of the surgical procedure • Increased connective tissue reaction

	• Complications due to twisting of the screw / resulting from pin bending or injury to tissue/bone due to imprecise placement • Complications or injury to the fabric due to sharp edges of the mesh or imprecise placement The following complications, risks and/or side effects may occur after implantation: • Large edema, hematoma formation; Pain and swelling • Postoperative bleeding • infections; Wound infection at the donor and/or recipient site • Abscess • Soft tissue/wound dehiscence • Neurological and vascular damage • Transient hypoesthesia of the mental nerve • Paresthesia • Loosening of the implants • Mesh exposure (mesh) (*specified only for meshes)* • Membrane exposure / perforation • Incorrect graft selection • Graft loss (e.g. bone block) / failure / resorption (total or partial) • Continuous bone resorption (stress shielding)

4.1 Other relevant aspects of security, including FSCA and FSN

N/A

5. Summary Clinical Evaluation and PMCF

The clinical evaluation conducted in accordance with the defined methodology has demonstrated that the products can be classified as WET (Well-Established Technology). In accordance with MDCG 2020-6, the common characteristics of WET devices can be considered to have been met.

The products have a relatively simple, conventional design with few further developments (e.g., use of standardized materials in accordance with ISO 5832-2 & -3, square drive in accordance with ASTM F543). The generic product groups are known to be safe and have not raised any safety concerns in the past. This statement is based on our market observation of comparable products. The performance characteristics of the products are well known. Furthermore, the products are part of the standard range with few further developments. This was confirmed, among other things, by the development of the SOTA. Furthermore, all products have a long-standing presence on the market. This applies both to the products that devemed has been distributing since 2006 (until 2020 as a distributor of the manufacturer Trinon Titanium GmbH, thereafter as manufacturer) and to the products being approved for the first time under the MDR.

The evaluated products generally do not exhibit any relevant new characteristics that could be considered new or significantly different compared to competing devices already legally marketed.

For the reasons stated above and due to the classification of the products as WET, data from other products could also be used in the clinical evaluation to demonstrate compliance with the essential safety and performance requirements.

Post-Market-Surveillance: The complaint statistics for our legacy devices (Microscrews / Titanium, Titanium Pins (excluding Solid Pins)) did not indicate any safety-related issues. Data for products being approved for the first time under the MDR were (understandably) not available.

Preclinical data: Mechanical comparative tests (all 4 test methods per ASTM F543) were conducted with comparable products for all 3 microscrew families. The analysis and evaluation of the results concluded that stability is comparable to that of products currently on the market. All acceptance criteria were met. For pins and meshes, justification was provided as to why no mechanical test procedures were performed.

Database screening: Systematic searches were conducted in the safety databases of the BfArM, FDA, and the National Agency for Medicines and Medical Devices of Romania (NAMMDR) for incidents or risks associated with our own products and comparators. No relevant events were found that had not already been assessed in the risk management process. For all known risks, the benefits outweigh the residual risk.

Literature review: Based on the systematic literature review, all parameters defined in the SOTA regarding the safety and performance of the products were substantiated.

The entirety of the data collected as part of the CER currently provides no reason to assume that the products under evaluation do not meet the general safety and performance requirements. Information relevant to the user, derived from the clinical evaluation, has been included in the instructions for use.

5.1 Summary of clinical data regarding the equivalence product

Not applicable, no clinical data were collected regarding equivalence product.

5.2 Summary of clinical data from trials conducted prior to CE marking

No data available.

5.3 Summary of clinical performance and safety

Compliance with safety and performance parameters							
Source / Literature	Product	No. of products	Level of evidence	No. of patients	Performance Parameters #1	Performance parameter #2	Safety parameters
Product to be evaluated: dev-os Microscrews / Titanium					Success rate: Fixation of bone graft > 95%	N/A	Screw loosening / removal: < 2% (if proven to be due to product problem)
[1] Török_2021	☒ devemed product ☒ Reference product ☐ comparable / related product	30	2b	20	☒ fulfilled ☐ no information ☐ not fulfilled	N/A	☒ fulfilled ☐ no information ☐ not fulfilled
[2] Referendaru_2018	☒ devemed product ☐ Reference product ☐ comparable / related product	2	4	1	☒ fulfilled ☐ no information ☐ not fulfilled	N/A	☒ fulfilled ☐ no information ☐ not fulfilled
[3] Lehmijoki_2016	☐ devemed product ☒ Reference product ☐ comparable / related product	9	4	9	☒ fulfilled ☐ no information ☐ not fulfilled	N/A	☐ fulfilled ☒ no information ☐ not fulfilled
[4] Yousif_2020	☐ devemed product ☒ Reference product ☐ comparable / related product	30	4	30	☒ fulfilled ☐ no information ☐ not fulfilled	N/A	☐ fulfilled ☒ no information ☐ not fulfilled
Product to be evaluated: dev-os Microscrews / INOX					Success rate: Fixation of bone graft > 95%	N/A	Screw loosening / removal: < 2% (if proven to be due to product problem)
[5] Khoury_2011	☐ devemed product ☒ Reference product ☐ comparable / related product	923	4	318	☒ fulfilled ☐ no information ☐ not fulfilled	N/A	☒ fulfilled ☐ no information ☐ not fulfilled
[6] Khoury_2019	☐ devemed product ☒ Reference product	200+	4	142	☒ fulfilled ☐ no information ☐ not fulfilled	N/A	☐ fulfilled ☒ no information ☐ not fulfilled

	☐ comparable / related product						
Product to be evaluated: dev-os Tenting-Screws / INOX					**Success rate: Fixation of bone graft > 95%**	**Success rate: Creation of room stabilization > 95%**	**Screw loosening / removal: < 2% (if proven to be due to product problem)**
[7] Lorusso_2022	☐ devemed product ☒ Reference product ☐ comparable / related product	2	4	2	☒ fulfilled ☐ no information ☐ not fulfilled	☒ fulfilled ☐ no information ☐ not fulfilled	☒ fulfilled ☐ no information ☐ not fulfilled
[8] Bahaa_2024	☐ devemed product ☐ Reference product ☒ comparable / related product	15	4	15	☒ fulfilled ☐ no information ☐ not fulfilled	☒ fulfilled ☐ no information ☐ not fulfilled	☒ fulfilled ☐ no information ☐ not fulfilled
Product to be evaluated: dev-os Titanium Pins / Solid-Pins					**Success rate: Membrane/mesh fixation > 95%**	**N/A**	**Pin loosening/removal and/or breakage < 2.0% (if proven to be due to product problem)**
[9] Valladao_2020	☐ devemed product ☒ Reference product ☐ comparable / related product	104(min.)	4	18	☒ fulfilled ☐ no information ☐ not fulfilled	N/A	☒ fulfilled ☐ no information ☐ not fulfilled
[10] Ortiz Vigón_2017	☐ devemed product ☒ Reference product ☐ comparable / related product	???	4	15	☒ fulfilled ☐ no information ☐ not fulfilled	N/A	☐ fulfilled ☒ no information ☐ not fulfilled
[11] Wang_2021	☐ devemed product ☒ Reference product ☐ comparable / related product	52(min.)	3	26	☐ fulfilled ☒ no information ☐ not fulfilled	N/A	☐ fulfilled ☒ no information ☐ not fulfilled
Product to be evaluated: dev-os Titanium Meshes					**Success rate: Augmentate fixation > 90%**	**Success rate: Room stabilization > 90%**	**Mesh exposure < 30.0% (if proven to be due to product issue)**
[12] Poli_2014	☐ devemed product ☒ Reference product	13(min.)	3	13	☒ fulfilled ☐ no information	☒ fulfilled ☐ no information	☒ fulfilled ☐ no information

	☐ comparable / related product				☐ not fulfilled	☐ not fulfilled	☐ not fulfilled
[13] Li_2020	☐ devemed product ☐ Reference product ☒ comparable / related product	30	4	21	☒ fulfilled ☐ no information ☐ not fulfilled	☐ fulfilled ☒ no information ☐ not fulfilled	☒ fulfilled ☐ no information ☐ not fulfilled
[14] Ribeiro Filho_2015	☐ devemed product ☐ Reference product ☒ comparable / related product	5(min.)	4	5	☒ fulfilled ☐ no information ☐ not fulfilled	☐ fulfilled ☒ no information ☐ not fulfilled	☒ fulfilled ☐ no information ☐ not fulfilled
[15] Torres_2010	☐ devemed product ☐ Reference product ☒ comparable / related product	43	1b	30	☒ fulfilled ☐ no information ☐ not fulfilled	☐ fulfilled ☒ no information ☐ not fulfilled	☒ fulfilled ☐ no information ☐ not fulfilled

The following table lists risks/complications and side effects that could be found in the identified and evaluated literature in the course of the development of the CEP and CER. These are usually treatment-related and not always or clearly attributable to the implants (microscrews, pins and meshes), as there can be numerous causes (e.g. user qualifications, patient situation and behavior) for the occurrence. Users are informed about these risks in the instructions for use.

Treatment-related risks/complications/side effects (quantitative)		
Complication	Quantitative data / incidence	Location / Source
Microscrews / Titanium		
Wound dehiscence	43% (3/7) patients	Kuster_2020 [16]
	14 % (1/7) patients, not product-related	Yousif_2020 [4]
Hematomas	14 % (1/7) patients	Kuster_2020 [16]
Wound infections at donor sites	2.8 % (3/86) patients	Sakkas_2016 [17]
Wound infections at the recipient site	5.7 % (6/86) patients	Sakkas_2016 [17]
Graft loss	6.7 % (7/86) patients	Sakkas_2016 [17]
	14 % (1/7) patients	Kuster_2020 [16]
Screw loosening	1.9 % (2/86) patients	Sakkas_2016 [17]
Temporary nerve damage	10.4 % (11/86) patients	Sakkas_2016 [17]
Microscrews / INOX		
Screw head exposure	5.3 % (26/318) patients	Khoury_2011 [5]
Wound dehiscence	1.2 % (5/318) patients	Khoury_2011 [5]
Exposure	5.3 % (26/318) patients	Khoury_2011 [5]
Infections	0.2 % (1/318) patients	Khoury_2011 [5]
Tenting-Screws / INOX		
Wound dehiscence	24.08% augmentations	Stumpf_2023 [18]
Screw Removal	9.07% (42/463) screws, but treatment-related	Stumpf_2023 [18]
Pins		
Wound dehiscence	33 % (5/15) patients	Ortiz Vigón_2017 [10]
Mesh		
Exposure	7.7 % (1/13) patients	Poli_2014 [12]
	6.7 % (2/30) augmentations	Li_2020 [13]
	28.5 % (6/21) patients	Torres_2010 [15]

Mesh Loosening / Removal	9.5 % (2/21) patients	Li_2020 [19]

dev-os Microscrews / Titanium

To demonstrate clinical safety and performance, studies on its own products [1][2] and reference products from competitors [3][4] were used. In total, more than 70 microscrews were inserted on 60 patients. Both the defined performance and safety parameters were met by all literatures. Either demonstrably through explicit information / quotations or at least derived.

Performance:

- Török (2021): Proven scheduled removal of screws after 4 months without loosening – clear fulfilment.
- Referendaru (2018): Integration of the grafts clearly proven, no signs of loosening or failure.
- Lehmijoki (2016) & Yousif (2020): Successful graft fixation is derived from follow-up data, implant survival, and stable augmented volumes.

Security:

- Török (2021): No postoperative complications. Screw removal according to plan – fulfilled.
- Referendaru (2018): No indications of relaxation; Screws in situ after 3 months – fulfilled.
- Yousif (2020): In one case, a screw that was not removed (off-label use) led to late infection → is not considered a product-specific complication.

The available literature data show that the safety and performance parameters defined in the CEP for the microscrews (titanium) have been largely confirmed in the context of augmentative surgical measures. The evidence ranges from prospective cohort studies (Oxford Level 2b) to case reports and case series (Oxford Level 4). The proven or inferred fulfillment of the parameters as well as the low complication rate underline the safety and clinical performance of the product. Individual restrictions regarding the significance of certain studies (e.g. small number of cases, retrospective designs) must be taken into account, but do not have a significant negative impact on the overall assessment.

In addition, the evaluated studies (CEP+CER) identified various treatment-related risks and complications – including wound dehiscence, infections or nerve damage – that can occur in the context of augmentative interventions. However, these complications are typically not directly attributable to the implant (microscrews) itself, but are often related to surgical technique, patient situation or anatomical location. The literature sources indicate that either no connection was made to the screws or they were off-label applications (e.g. lack of screw removal contrary to IFU). The corresponding risks are addressed in the instructions for use and are within the scope of what can be expected clinically with comparable procedures.

dev-os Microscrews / INOX

To demonstrate clinical safety and performance, 2 studies on reference products from competitors were used. In total, over 1100 microscrews were inserted on 460 patients. The defined performance parameter could be demonstrably fulfilled by both literatures. The safety parameter by one literature (other literature unspecified).[5] [6]

Performance:

- Khoury (2011): Stable bone block fixation and planned implant placement in all 489 augmentations (n=736). No evidence of graft failure.
- Khoury (2019): After 3 months of removal of the screws and scheduled implantation of 356 implants. Vertical bone gain Ø 7.6 mm, high implant survival rate (98.7 %).

Security:

- Khoury (2011): No screw fractures, no material failure, no metal eyelet, all screws can be easily removed ⇨parameters are met.
- Khoury (2019): No explicit information on screw loosening or loss, but no evidence of complications due to screw failure.

The literature review confirms that the safety and performance parameters defined in the CEP for devemed stainless steel microscrews (INOX) are adequately substantiated by data from clinical studies on reference products (Microscrew® system, Storz am Mark). The analyzed studies document a high clinical success rate in graft fixation and show no evidence of product-related screw loosening or loss, which means that the safety parameter can also be considered met. Although both studies are formally assigned to evidence level 4, their clinical significance for the product to be evaluated is high due to the large number of screws used, the number of patients and long-term observation periods (up to 10 years).

In addition, treatment-related risks (e.g. wound dehiscence, infections, screw exposure) were also identified as part of the literature review (CEP+CER). These complications occurred within the expected range and can be attributed primarily to surgical factors, patient characteristics (e.g. smoking status) or localization. In the studies, they were not causally attributed to the implant material or product failure. The IFUs of devemed products explicitly point out these risks to users.

dev-os Tenting-Screws / INOX

To demonstrate clinical safety and performance, 2 case series of reference products of competitors [7] or comparable products [8] were used. A total of 17 Tenting-Screws were used on 17 patients.

Performance:

- Lorusso (2022): In both cases, stable bone conditions, screws removed after 6 months as planned, no exposure or inflammation – parameters met.
- Bahaa (2024): Significant horizontal bone growth (+2.62 mm / +76.3%), removal of screws during implant placement – parameters met.

Security:

- Lorusso (2022): No complications, no screw loosening or failure described.
- Bahaa (2024): No explicit statements on screw safety, but no complications mentioned → safety parameters derived fulfilled.

The present literature review shows that the safety and performance parameters defined in the CEP for devemed Tenting-Screws are confirmed by clinical data from two case series with a total of 17 patients. Both studies prove that the Tenting-Screws enable successful graft fixation as well as room stabilization in the sense of the augmentative objective and thus meet the performance parameter. The safety parameter is also considered to be met – explicitly in one study, in the other derived from a lack of evidence of product-related complications. Critically, it should be noted that the clinical evidence for the Tenting-Screws is still low overall, which is why unfortunately "only" two case series could be evaluated.

In the literature review (CEP+CER), treatment-related risks such as wound dehiscence or exposure of the screw head were documented. However, these were not causally attributable to the product itself, but were to be interpreted as typical, known side effects of augmentative surgical interventions. The instructions for use of devemed Tenting-Screws point out such risks so that they are appropriately addressed in a clinical context.

Titanium Pins

To demonstrate clinical safety and performance, studies and case series on reference products from competitors were used. In total, at least 165 pins were inserted on 59 patients. [9][10][11]

Performance:

- Valladão (2020): Significant bone growth occurred in 52 defect regions (horizontal +5.9 mm / vertical +5.6 mm), all cases were released for implantation – parameters were met (derived).
- Ortiz-Vigón (2017): Pins removed after 26 weeks; in 13/15 cases, successful bone augmentation with +4.12 mm – parameters met (demonstrably).
- Wang (2021): No explicit indication of success of pin fixation, but clinically successful GBR without complications – parameters cannot be directly assessed, but no contradiction to the objective.

Security:

- Valladão (2020): No complications, no exposure, no pin problems – parameters met (derived).
- Ortiz-Vigón (2017): Two cases of dehiscence led to the removal of the augmentation, but no relation to the pins – parameters not clearly assessable, but no contradiction.
- Wang (2021): Not a single case of complication – parameters not demonstrably fulfilled due to lack of information, but implicitly fulfilled.

The available literature data prove that the safety and performance parameters defined in the CEP for devemed titanium pins are adequately supported by clinical studies with comparable products. In all three studies evaluated, the pins were used to fix membranes or grafts as part of guided bone regeneration (GBR). The performance parameter – defined as successful fixation and room stabilization > 95% – is either described directly or can be derived from the success of the treatment. The safety parameter – loosening, removal or breakage < 2% in the case of a product-related cause – is explicitly fulfilled in one study and indirectly in another; in a third study, there is no information, but no indications of product-specific complications.

The entirety of the studies considered covers clinically relevant indications and realistic application environments. While two of the three studies only formally achieve evidence level 4, their results are consistent and cover different aspects of safety and performance (e.g., soft tissue healing, membrane stability, complications). The study by Wang et al. provides additional backing at evidence level 3b.

In addition, the studies considered in CEP+CER also document treatment-related risks, such as soft tissue dehiscence. However, these complications are not due to the pins used, but are rather classified as procedural side effects. The instructions for use of the devemed titanium pins take such risks into account and advise users accordingly.

Titanium Meshes

To demonstrate clinical safety and performance, 1 study on reference products of competitors [12] and 3 studies or case series on comparable products [13] [14] [15] were used. In total, at least 91 meshes were used on 69 patients.

Performance:

- The titanium meshes were successfully used in all four studies. Augmentate fixation was given in any case, usually accompanied by CBCT or histological evidence.
- Although room stabilization was not explicitly named in every study, it was indirectly confirmed by the achievement of stable bone volume.

Security:

- Poli (2014): Mesh exposure 1/13 cases (7.7%)
- Li (2020): Mesh exposure 2/21 cases (9.5%)

- Ribeiro-Filho (2015): no expositions
- Torres (2010): Mesh exposure 6/21 cases in the control group without PRP (28.5%)

The present literature review shows that the safety and performance parameters defined in the CEP for devemed titanium meshes in the context of augmentative bone surgery are sufficiently substantiated by several studies with different study designs and mesh products. The analyzed sources confirm that titanium meshes are able to provide stable fixation of the augmentate, as well as effective space stabilization. The safety parameter – mesh exposure < 30% (if product-related) – was not exceeded in any of the studies.

The overall evidence is based on a combination of high-quality randomised evidence (Level 1b) and supplementary clinical case series. Despite heterogeneity in study design and patient numbers, a consistent picture emerges with regard to clinical safety and performance of the titanium meshes.

Treatment-related risks – especially mesh exposures or soft tissue dehiscences – have been observed in several studies, but are typical for this indication and are interpreted as surgical-technical or patient-related. These risks are taken into account accordingly in the instructions for use of devemed titanium meshes.

5.4 Ongoing and/or planned PMCF actions

Ongoing and/or planned PMCF measures	**Evaluation/Content**
Evaluation of sales and complaint data	So far, no complaint has been reported.
Corrective and preventive actions	So far, no product-related CAPAs have been opened.
Vigilance data Reportable events / reports on safety in the field	To date, no reportable events and/or FSN/FSCA have been received/opened.
Data on adverse events for similar products	A search was carried out at the BfArM, MAUDE and National Agency for Medicines and Medical Devices of Romania database. No reports were found and evaluated that indicate adverse events with similar products or our products.
Review of scientific literature through systematic literature research	A clinical evaluation and monitoring of the results took place. The results were incorporated into the instructions for use and risk management and are monitored in the course of PMCF activities.

6. Diagnostic / therapeutic alternatives

The products evaluated in this CER ultimately all serve as aids in various jawbone augmentation procedures. Which augmentation procedure is ultimately used depends on various factors, such as: the preferences or training of the surgeon, the patient's decision after the surgeon has informed him in the case of several options including cost consideration, or the initial situation. Among other things, it is important to consider where the bone has to be built up (upper or lower jaw, anterior, posterior or molar) and how much bone resorption has already progressed. In the following, both alternative augmentation procedures and alternative aids (in the sense of implants/"competing products") will be presented and evaluated.

Alternative augmentation procedures

Sinus lift (internal & external)
Internal sinus lift is a minimally invasive method of bone augmentation in the posterior region of the maxillary tooth that is used when the residual bone height is moderately reduced (typically 5–8 mm). In this process, the floor of the maxillary sinus or the Schneider membrane is slightly lifted through a small osteotome window or by means of special instruments (e.g. osteotomes or modern hydrodynamic systems) and bone material is inserted underneath. Access is transcrestal, i.e. via the implant bed.

In the external sinus lift, a lateral window to the maxillary sinus is prepared, the Schneider membrane is lifted and bone material is inserted. The method allows for significant vertical bone recovery, but is more invasive and associated with higher risks and longer healing time.

The main limitation of the techniques is that they can only be performed in the maxillary posterior region. Other limitations include:

- Restricted volume augmentation (>4-5 mm vertical)
- High technical sensitivity (injury to Schneider's membrane)

Due to the limitations, the procedures can never completely replace augmentation procedures using screws, pins/membranes or meshes.

Bone Spreading
In bone spreading, the remaining jaw ridge is divided into two parts (incomplete division) and the resulting gap is then spread/stretched. The implants advertised here act as placeholders. Remaining cavities are ideally filled with Platelet Rich Fibrin (PRF).

However, the range of application of the technique is limited: bone spreading can only be used if the crestal bone supply in the jaw does not fall below 3 mm horizontally. This is because the incision during the procedure alone usually "costs" about 1 mm of bone mass. The remaining 1 mm bone wall on each side is absolutely necessary so that the bony situation does not become unstable. In addition, the procedure also requires a minimum value in height: For successful bone spreading, 10 mm cutting depth without obstacles such as an adjacent nasal floor, tooth roots, nerves, displaced teeth or other vulnerable structures are indicated [20].

Bone Splitting
In contrast to bone spreading, in which the jawbone is not completely split, bone splitting involves complete splitting by means of an osteotomical longitudinal section. The resulting gap can be filled with augmentates, as with bone spreading.

The scope of application of this technique is also limited, since the vertical height of the bone supply must be given and the transverse width of the alveolar ridge should not be less than 3 mm.[21]

Due to their limitations, both bone spreading and bone splitting can never completely replace augmentation procedures using screws, pins/membranes or meshes.

Distraction osteogenesis
Distraction osteogenesis (synonym: callus distraction) is a surgical procedure, the literal translation of which already explains the procedure: new bone formation by pulling apart. A fracture gap surgically created by an osteotomy (surgical separation of bone or the excision of a piece of bone) is stimulated to form callus or bone. In addition, a controlled tensile force is exerted on the artificially created gap by means of a special apparatus on the bone fragments (bone fragments on both sides of the gap), the so-called distractor, so that the fracture surfaces are

separated (pulled apart) by about 0.8 mm to 10 mm per day. In this precisely measured daily distraction path, the gap is continuously bridged with new callus, so that a steady elongation of the affected bone is achieved.[22]

Vertical distraction for alveolar process extension in the lower jaw is mainly carried out in the frontal area. In the posterior region, this application is indicated only in exceptional cases and is often combined with a displacement of the inferior alveolar nerve. In this case, the procedure should only be used in cases of extreme bone loss. In the upper jaw, the main area of application of this technique is also the anterior tooth area. In the posterior region, however, the use of the procedure is limited by the anatomical arrangement of the paranasal sinuses.[23]

Alternative aids ("competing products")

Absorbable screws

Absorbable screws are an integral part of modern augmentation techniques in oral surgery, especially in the fixation of autogenous bone grafts or bone substitute materials. Their greatest advantage is their biodegradation, which eliminates the need for a second intervention for removal.

Quereshy et al. (2010) [24] were able to show in a pilot study that the survival rate of bone grafts fixed with absorbable screws (2.0 mm) was 100% as well as for grafts fixed with titanium screws (1.5 mm).

However, there are challenges in mechanical load-bearing capacity, especially in vertical augmentations or in the region with high chewing force. In their study, Altan et al. (2016) investigated the nanohardness and elastic modules of absorbable screws compared to titanium screws. The absorbable screws proved to be softer and more flexible. The cost aspect of the significantly more expensive absorbable screws should not be ignored either.[25]

Costum bone regeneration (CBR) using custom-made CAD-CAM meshes

The CBR technique (Cortical Bone Reconstructive Technique) using CAD/CAM-manufactured meshes is an innovative approach to precise three-dimensional bone augmentation. An individual, digital mesh based on the DVT/CT image of the patient is designed and manufactured in order to guide bone substitute material safely and dimensionally stable.

The great advantage of custom-made meshes is that they no longer have to be processed by the user compared to "cut-to-size" meshes. However, they require longer and precise surgical planning. Also due to the significantly higher costs, they cannot currently completely replace "cut-to-size" meshes.

PTFE diaphragms (titanium reinforced)

Membranes as well as meshes play a role in GBR technology. They prevent soft tissue from migrating into the bone defect, so that only bone can regenerate there. Titanium-reinforced PTFE membranes attempt to compensate for the stability disadvantage of conventional membranes compared to titanium meshes by installing titanium reinforcement in the membrane. In the case of particularly large defects with missing retaining walls and especially in connection with vertical augmentations, they can nevertheless reach their limits. [26]

Maiorana et al. (2021) investigated clinical and histological differences in bone regeneration after preprosthetic vertical bone augmentation with titanium-reinforced dense PTFE membrane compared to titanium mesh (thickness 0.12mm, perforation 0.5mm; manufacturer: AON Implant, Italy) in a prospective split-mouth study.[27]

In 2 out of 10 augmentations, premature exposure of the meshes occurred, which in one case led to an infection that had to be treated with antibiotics. The meshes have not been removed. The suspected cause of exposure is stiffness and the presence of sharp edges. Vertical bone augmentation was higher, though not significant, in the PTFE group. If no exposure was present, similar histological results were observed. In the case of wound dehiscence, greater absorption has been observed. In all cases, successful vertical augmentation could be demonstrated.

Cucchi et al. (2019) found in a study that GBR with non-absorbable membranes or with a Ti-mesh with absorbable membranes provided a similar degree of bone augmentation, as shown by histological and histomorphometric analyses.[28]

As already mentioned at the beginning, titanium meshes are particularly in demand when large defects are to be augmented or recontoured. In this case, the mesh (in addition to separating the soft tissue from the augmented area) has the task of providing the contour for augmentation and stabilizing the augmentation. Therefore, titanium-reinforced membranes cannot completely replace titanium meshes.

7. Suggested user profile and training

Oral surgeons
Maxillofacial surgeons

8. Reference to all harmonised standards and common specifications applied

8.1 Common Specifications

None

8.2 Harmonised standards under Regulation (EU) 2017/745

Standard	Description
EN 285:2015	Sterilization – Steam sterilizers – Large sterilizers A1:2021
EN ISO 10993-9:2021	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2019)
EN ISO 10993-10:2023	Biological evaluation of medical devices – Part 10: Tests for skin sensitisation (ISO 10993-10:2021)
EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
EN ISO 10993-17:2023	Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)
EN ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020) EN ISO 10993-18:2020/A1:2023
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021.
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
EN ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021)
EN ISO 11137-1:2015, EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137- 1:2006, including Amd 1:2013)
EN ISO 11737-1:2018, EN ISO 11737-1:2018/A1:202	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737- 1:2018)
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)

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