# UNI-Smile Distractor Smile Distraction

"Giving people a nice Smile."





# **TABLE OF CONTENT**

Who are we

Palatal distraction dev

Features

Surgical technique

Product information

Patient information



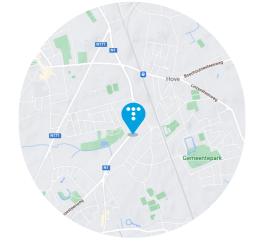


|       | 4  |
|-------|----|
| vices | 5  |
|       | 6  |
|       | 8  |
|       | 10 |
|       | 13 |

## Who are we?

### **Our Company**

Titamed is a market leader in standardized craniomaxillofacial (CMF) solutions. We have over 35 years of experience in the design, development and manufacturing of superior, innovative, high quality and user-friendly CMF products. This has been accomplished with the cooperation, experience and commitment of outstanding craniomaxillofacial surgeons from leading clinics.



### Locations

We are based in Belgium, the heart of Europe, with an excellent reputation in the field of healthcare, biotech and medical devices.

### **Our products**



#### **SMART FIXATION**

Smart Fixation provides internal fixation of cranial and facial bones during cranio- and maxillofacial procedures.



#### SMILE DISTRACTION

The palatal distractors are designed to widen the upper jaw, allowing surgeons to deliver outstanding improvements to the facial features of their patients.



#### PERSONALIZED IMPLANTS

For patient-specific implants, Titamed has partnered with Avinent to provide surgeons with a complete CMF solution.

**UNI-Smile Distractor** 

# **Palatal distraction devices**

### Indication

Surgically assisted rapid maxillary expansion (SARME) is needed in skeletally matured patients (closed midpalatal suture), to correct a transverse maxillary deficiency or hypoplasia. This is frequently seen in adolescents and adults. Those patients are often seen with a unilateral or bilateral posterior crossbite and anterior dental crowding.

## Distraction

### Type and use

### **UNI-SMILE DISTRACTOR:**

The most commonly used type.



#### SMILE EXTRA DISTRACTOR:

For cases requiring significant expansion.



#### **SMILE 3 DISTRACTOR:**

For pathological small upper jaws and clefts.





Distraction osteogenesis relies on the body's natural ability to heal fractures. It is a process of new bone formation where a transpalatal distractor gradually pulls apart two pieces of bone. The gradual separation is not painful, and new bone grows to fill the gap.

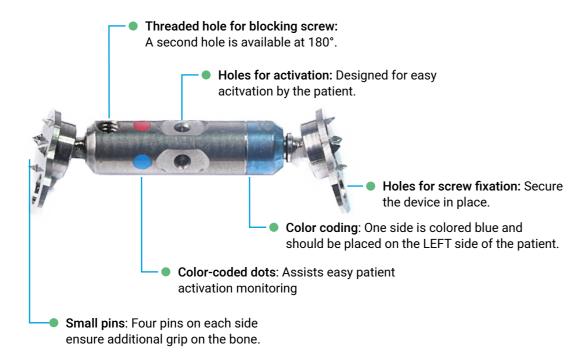


# **Features**

### Mechanism



### Module



**UNI-Smile Distractor** 

# **Features**

### **Features**

- Unmatched Comfort & Hygiene: The smallest module on the market, designed to minimize discomfort while ensuring optimal oral hygiene. Seffortless Patient Activation: User-friendly design, enabling patients to expand their distractor intuitive and effortless.
- Anatomical Fit: Self-adjusting plates conform naturally to the bone structure, enhancing stability and reducing surgical complexity.
- Reliable & Durable: Proven track record for over 20 years. High-quality materials and precision engineering ensure longevity and stability throughout the treatment period.

2018 - Journal of Cranio-Maxillo-Facial Surgery; Bone changes on lateral cephalograms and CBCT during treatment of maxillary narrowing using palatal osteodistraction with bone-anchored appliances.

2017 - Journal of Cranio-Maxillofacial Surgery; The effects of surgically assisted rapid maxillary expansion (SARME) on the dental show and chin projection.

2017 - Journal of Oral and Maxillofacial Surgery; Following Surgically Assisted Rapid Palatal Expansion, Do Tooth-Borne or Bone- Borne Appliances Provide More Skeletal Expansion and Dental Expansion?

Link to complete list of publications.

 $\bullet \bullet \bullet$ 





# **Surgical procedure**

### Sequence of the surgery

- Corticotomies: Lateral, midline, and (if necessary) posterior disjunction. 1.
- 2. Placement of the UNI-Smile Distractor: Fixed with self-drilling screws between teeth (14)-15-16 and (24)-25-26.

INCISION

downward. as illustrated.

Δ Rev. SP-022



**UNI-Smile Distractor** 

Surgical procedure





IT0128

IT0314

#### **KEEP IN MIND**

- 1. is no automatic stop.
- 2. A minimum palatal distance of 21,5 mm is necessary to place the smallest UNI-Smile Distractor.

### Sequence of the distraction

- Surgery: (as outlined above) 1.
- 2. Activation period: Begins one week post-surgery. Remove the blocking screw and expand until resistance is felt, then turn once or twice more.
  - During activation (1-2 weeks), patients should turn the device twice daily, 1/4 turn per time (~0.5 mm/day).
  - With each turn, a new color appears. •
- 3. Consolidation period: Once the desired expansion is achieved, reinsert the blocking screw firmly. The distractor must remain in place for 3 to 6 months.

#### Blue mark ALWAYS to the left!

IT0400





### PLACEMENT

The abutment plates must be placed horizontally, with the blue side always on the left.

A cross-palatal incision or L-incision is recommended,

placed between the premolar and molar or between the premolars. The incision should be made 1 cm

The correct distractor module size can be measured

To maximize potential expansion space, it is advised to

bone to bone with the fitting models IT0400.

use the largest possible module size.

Ensure the wings of the distractor are completely and evenly screwed in to avoid losing expansion space.

The Smile Distractor is secured with selfdrilling screws DSSA06 or DSSA07 using screwdriver IT0315.

IT0315



#### ACTIVATION

The surgeon activates the Smile Distractor until an opening of ~1 mm appears between the front teeth.

Use key instrument IT0314 to turn the distractor from front to back.

#### **BLOCKING SCREW**

The blocking screw D002 is inserted into one of the two threaded holes using screwdriver IT0128.

The blocking wherscrew must be firmly fixed using wrist force.

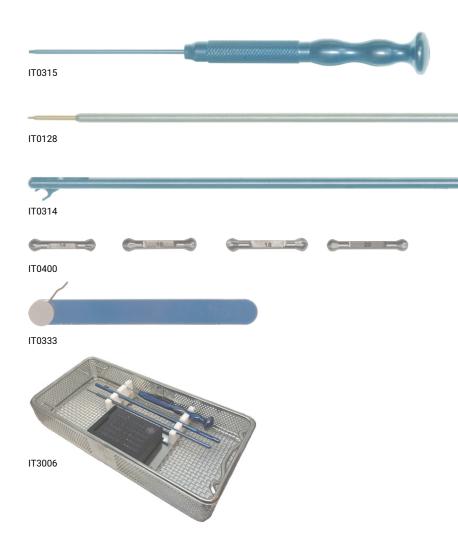
The wings of the distractor can be turned completely loose of the distractor module. There

Δ -022 Rev. ģ

Tip: Our patient information can be found on our website www.titamed.com.

# **Product information**

### Instruments



| Cat. No. | Description                       |
|----------|-----------------------------------|
| IT0315   | Hexagon Screwdriver               |
| IT0128   | Square Screwdriver PHI, long      |
| IT0314   | Key for UNI-Smile and Smile 3     |
| IT0400   | Fitting models, UNI-Smile         |
| IT0333   | Patient Key UNI-Smile and Smile 3 |
| IT3006   | Container UNI-Smile, 24 x 12cm    |

**UNI-Smile Distractor** 

# **Product information**

### Distractors



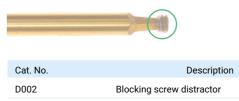
| Cat. No.         | Description                  | Distractor closed | Distractor open |
|------------------|------------------------------|-------------------|-----------------|
| DSA014           | UNI-Smile Distractor, 14mm   | 21.5 mm           | 31.5 mm         |
| DSA016           | UNI-Smile Distractor, 16mm   | 23.5 mm           | 35.5 mm         |
| DSA018           | UNI-Smile Distractor, 18mm   | 25.5 mm           | 39.5 mm         |
| DSA020           | UNI-Smile Distractor, 20mm   | 27.5 mm           | 43.5 mm         |
| * optional DSA02 | t optional DSA022 and DSA024 |                   |                 |

### **Screws**

### mm

| Cat. No.                                | Description                      | Ø      |
|---|----------------------------------|--------|
| DSSA06                                  | Bone screw, self-drilling, L=6mm | 2.3 mm |
| DSSA07 Bone screw, self-drilling, L=7mm |                                  | 2.3 mm |
| * used with screwdriver IT0315. hexagon |                                  |        |

# Blockingscrew



D002-4 Blocking screw distractor, set of 4 p \* used with screwdriver IT0128, square

10



|     | Ø      |  |
|-----|--------|--|
|     | 2.0 mm |  |
| pc. | 2.0 mm |  |



# **Product information**

### **Box content**



| IT0128Square Screwdriver PHI, long1IT0314Key for UNI-Smile and Smile 31IT0315Hexagon Screwdriver1IT0400Fitting models, UNI-Smile1DSA014UNI-Smile Distractor, 14mm1DSA016UNI-Smile Distractor, 16mm1DSA018UNI-Smile Distractor, 18mm1DSA020UNI-Smile Distractor, 20mm1DSSA06Bone screw, self-drilling, L=6mm4DSSA07Bone screw, self-drilling, L=7mm4   |        |          |   |               |
|---|--------|----------|---|---------------|
| IT0314 Key for UNI-Smile and Smile 3 1   IT0315 Hexagon Screwdriver 1   IT0400 Fitting models, UNI-Smile 1   DSA014 UNI-Smile Distractor, 14mm 1   DSA016 UNI-Smile Distractor, 16mm 1   DSA018 UNI-Smile Distractor, 18mm 1   DSA020 UNI-Smile Distractor, 20mm 1   DSSA06 Bone screw, self-drilling, L=6mm 4   DSSA07 Bone screw, self-drilling, L=7mm 4  | IT3006 | Cat. No. | Description                             | Max. quantity |
| IT0315 Hexagon Screwdriver 1   IT0400 Fitting models, UNI-Smile 1   DSA014 UNI-Smile Distractor, 14mm 1   DSA016 UNI-Smile Distractor, 16mm 1   DSA018 UNI-Smile Distractor, 18mm 1   DSA020 UNI-Smile Distractor, 20mm 1   DSSA06 Bone screw, self-drilling, L=6mm 4   DSSA07 Bone screw, self-drilling, L=7mm 4   | 2      | IT0128   | Square Screwdriver PHI, long            | 1             |
| IT0400 Fitting models, UNI-Smile 1   DSA014 UNI-Smile Distractor, 14mm 1   DSA016 UNI-Smile Distractor, 16mm 1   DSA018 UNI-Smile Distractor, 18mm 1   DSA020 UNI-Smile Distractor, 20mm 1   DSSA06 Bone screw, self-drilling, L=6mm 4   DSSA07 Bone screw, self-drilling, L=7mm 4  | 2      | IT0314   | Key for UNI-Smile and Smile 3           | 1             |
| Normality of the structure | 2      | IT0315   | Hexagon Screwdriver                     | 1             |
| Image: Second | 2      | IT0400   | Fitting models, UNI-Smile               | 1             |
| No. 2018 UNI-Smile Distractor, 18mm 1   No. 2018 UNI-Smile Distractor, 20mm 1   No. 2019 UNI-Smile Distractor, 20mm 1   No. 2019 UNI-Smile Distractor, 20mm 1   No. 2019 Bone screw, self-drilling, L=6mm 4   No. 2019 Bone screw, self-drilling, L=7mm 4   | 2      | DSA014   | UNI-Smile Distractor, 14mm              | 1             |
| Image: Second | 2      | DSA016   | UNI-Smile Distractor, 16mm              | 1             |
| Image: State of the state  | 2      | DSA018   | UNI-Smile Distractor, 18mm              | 1             |
| DSSA07   Bone screw, self-drilling, L=7mm   4   | 3      | DSA020   | UNI-Smile Distractor, 20mm              | 1             |
|   | 3      | DSSA06   | Bone screw, self-drilling, L=6mm        | 4             |
| D002-4 Blocking Screw Distractor, set of 4 pc. 1  | 3      | DSSA07   | Bone screw, self-drilling, L=7mm        | 4             |
| 3   | 3      | D002-4   | Blocking Screw Distractor, set of 4 pc. | 1             |

**UNI-Smile Distractor** 

# **Patient information**

Your doctor has provided you with a Smile Distractor to widen your upper jaw.

#### Treatment phases:

- Placement + rest (1 week)
- Activation period (1 3 weeks)
- Retention period (3 6 months)

The exact duration of each phase is determined by your doctor.





Before the widening

Smile distractor in use

For detailed patient information, visit <u>www.titamed.com</u>.





6 months afterwidening







### Headquarters:

Titamed Mechelsesteenweg 297 F 2550 Kontich Belgium

tel: +32 (0)3 289 51 56 email: info@titamed.com website: www.titamed.com version:SP-608 rev B