



# **TRANSPALATAL DISTRACTOR 3.4499**



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## SYMBOLS DESCRIPTION

	Titanium or titanium alloy	H	H length [mm]
	Cobalt		Angle
	Left	88 - 340	available lengths
R	Right	4-22	Available number of holes
R	Available versions: left/right	1.8	Thickness [mm]
n	Length	1:1	Scale 1:1
	Torx drive		Number of threaded holes in the shaft part of the plate
	Torx drive cannulated		Number of locking holes in the plate
	Hexagonal drive	VA	Variable angle
	Hexagonal drive cannulated		Cortical
	Cannulated		Cancellous
3	Locking	Ster Non Ster	Available in sterile/ non- sterile condition
1	Diameter [mm]		Refer to surgical technique
7	Caution - pay attention to a special procedure.		
	Perform the activity under X-Ray control.		
	Information about the next stages of a procedure.		
	Proceed to the next stage.		
	Return to the specified stage and repeat the activity.		
	Before using the product, carefully read the Instructions for Use. It contains, related to the use of the product.	among others, inc	dications, contraindications, side effects, recommendations and warnings
	The above description is not a detailed instruction of conduct. The surgeon	decides about ch	loosing the operating procedure.

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The manufacturer reserves the right to introduce design changes. Updated INSTRUCTIONS FOR USE are available at the following website: ifu.chm.eu

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#### 1. INTRODUCTION

The presented range of implants is made of materials in accordance with ISO 5832 standards.

The system includes:

- implants,
- instrument set used in the surgery,
- surgical technique.

#### **Indications**

Correction of the deformities of the maxilla, especially in skeletally mature patients.

#### **Plate selection**

Distraction microplates are available in various length variants. This allows for optimal selection of the implant to the deformity type. The implants are attached to the bone with bone microscrews of 2.0ChMP system.

It is not allowed to profile the implants (fixing plates included).



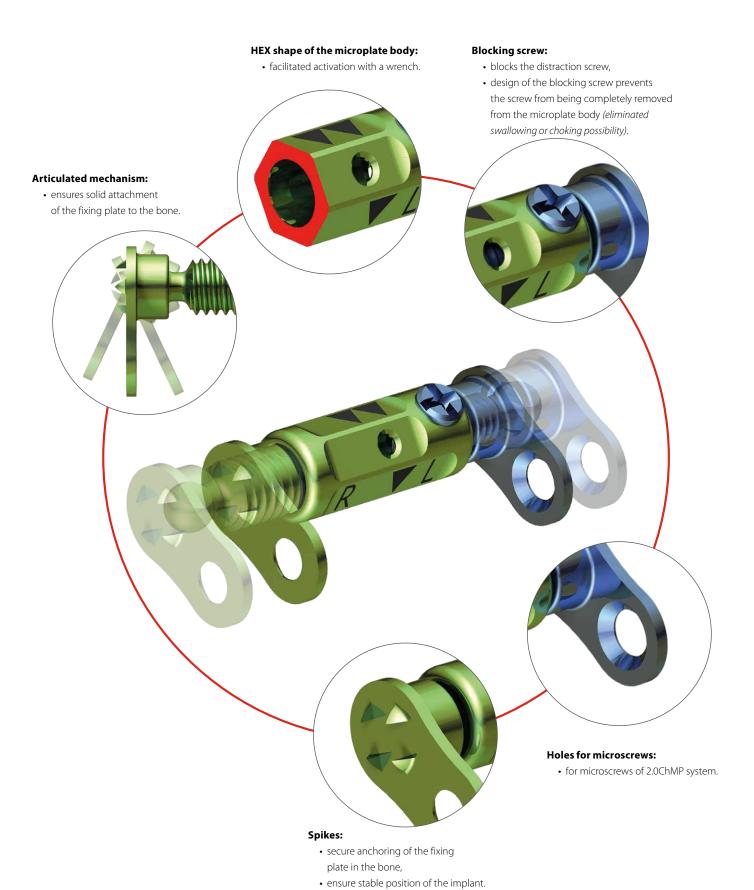
Before using the product, carefully read the Instructions for Use. It contains, among others, indications, contraindications, side effects, recommendations and warnings related to the use of the product.



The above description is not a detailed instruction of conduct. The surgeon decides about choosing the operating procedure.

## 2. IMPLANT DESCRIPTION

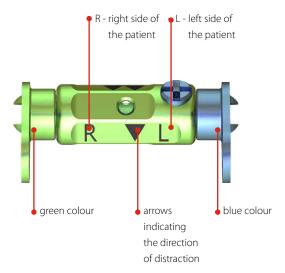






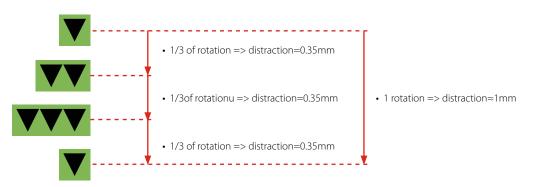
#### **Markings on the implant**

Patient-side identification system has been introduced: R - right side of the patient, L - left side of the patient. In addition, the fixing plates were colour-coded: right plate - green colour; left - blue.



### **Diagram of subsequent rotation sequences**

 $Distraction\ is\ performed\ by\ rotating\ the\ implant\ body\ in\ the\ direction\ indicated\ by\ the\ arrows.\ Schematic\ description\ of\ subsequent\ rotation\ sequences:$ 



## 3. SURGICAL TECHNIQUE

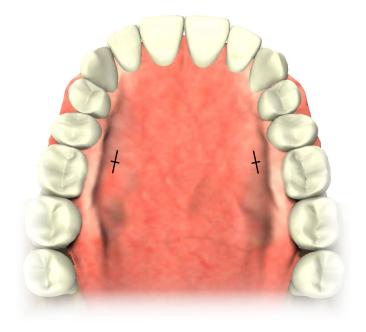
Perform planned osteotomies of the maxilla.



NOTE: It is recommended to place a gauze in the mouth to retain any small element in the event it is dropped in the mouth.

## 3.1. SURGICAL APPROACH

Perform an L-shaped or cross-incision of the palate between premolars and molars or between premolars. The length of the horizontal incision should be about 10mm parallel to the teeth, while the vertical one - about 3mm perpendicular to the teeth.



#### 3.2. IMPLANT SELECTION

Use trials  $\[ [43.4499] \]$  and forceps  $\[ [30.3303] \]$  to choose an implant of an adequate length.

low II	43.4499.017
	43.4499.020
Lon D.	43.4499.023
0.5	43.4499.026
	30.3303.000



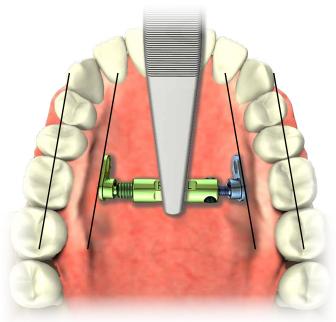
#### 3.3. IMPLANT INSERTION

Use dissecting forceps **[30.3303]** to position the implant on the bone. Set the fixing plates in horizontal position.





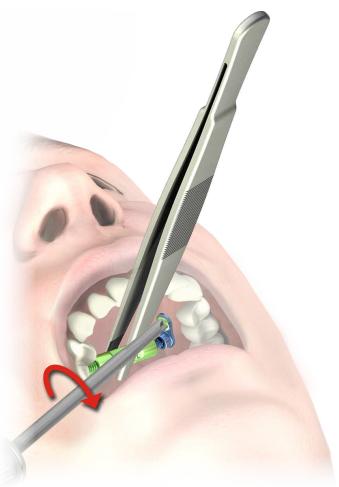
NOTE: Make sure the plate is positioned correctly: the left (L) side (blue) should be placed on the left side of the patient.



#### **3.4.** MICROSCREW INSERTION

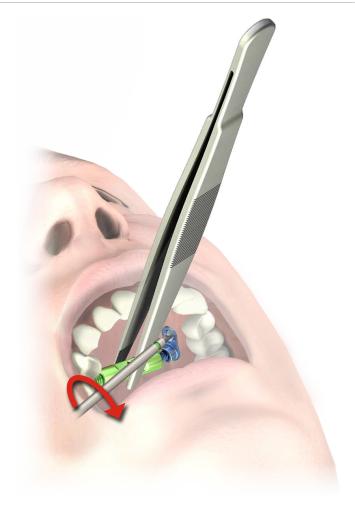
Use the quick coupling handle **[40.6405]** and a screwdriver tip X **[40.6449]** to insert the microscrews, of the appropriate length, in the fixing plate holes.





If need be, use the 1.25/15 drill [40.6422] to drill a hard bone.

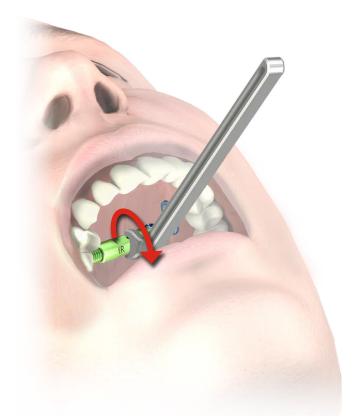
40.6422.600
40.6422.608



#### 3.5. ACTIVATION

Use the flat wrench [40.8402] to activate the distraction microplate until diastema of about 1mm is observed.







Activate the implant in accordance with the direction indicated by the arrows - refer to point 2 IMPLANT DESCRIPTION.

#### 3.6. LATENCY PERIOD

Use the quick-coupling handle **[40.6405]** and screwdriver tip X **[40.6449]** to tighten up the blocking screw and block the implant during the latency period.





 $\mbox{{\it NOTE}:} Tighten clockwise. Do not overtighten the blocking screw to avoid damage to the thread.$ 



The latency period lasts about 1 week. The doctor decides on the length of the latency period.



#### 3.7. DISTRACTION

Following the latency period, begin the distraction.

a) Use the quick-coupling handle **[40.6405]** and screwdriver tip X **[40.6449]** to unlock the blocking screw.

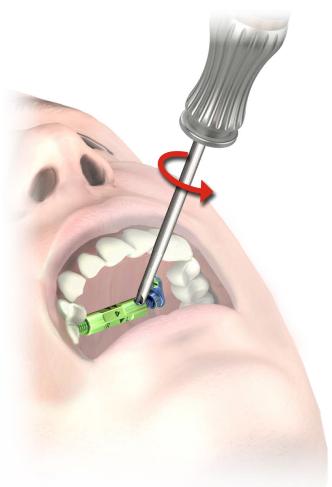




NOTE: Do not apply excessive force while unlocking since the blocking screw is secured against complete removal from the implant body.



NOTE: Unscrew the screw counterclockwise.

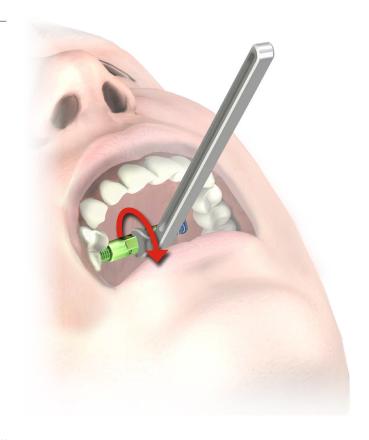


b) Use the flat wrench [40.8402] to rotate the implant body until resistance is felt.



40.8402.100

c) Make one or two rotations of the microplate body



d) In the distraction period, the patient performs 1/3 of the rotation twice a day using the flat wrench [40.8402].



40.8402.100

2 times a day x 1/3 rot. => distraction = 0.7 mm

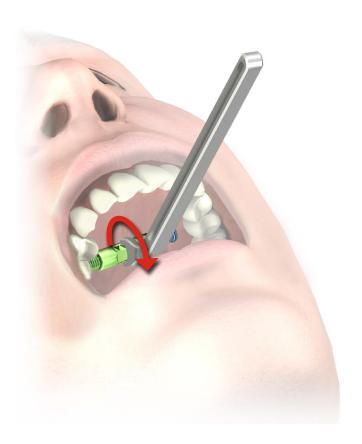


Detailed diagram of the rotation sequences - refer to point 2  $\ensuremath{\mathsf{IMPLANT}}$  DESCRIPTION.



The doctor determines the size of the entire and daily distraction. Depending on the size of the intended distraction, this period last from 1 to 4 weeks.

The doctor provides the patient with a distraction calendar for recording the sequence of rotations performed.



#### 3.8. CONSOLIDATION PERIOD

Once the planned expansion is accomplished, the new bone must be given time to consolidate. Block the distraction microplate with blocking screw using screwdriver tip X **[40.6449]** and quick-coupling handle **[40.6405]**.





NOTE: Tighten clockwise. Do not overtighten the blocking screw to avoid damage to the thread.



The consolidation period lasts about  $3\div 6$  months. The doctor decides on the length of the consolidation period.



## 4. IMPLANT REMOVAL

The doctor decides to remove the implant.

To remove the implant:

- a) unlock the blocking screw,
- b) loosen the microscrews (do not remove them completely),
- c) loosen the body of the implant
- d) remove microscrews and distraction microplate.



NOTE: It is recommended to place a gauze in the mouth to retain any small element in the event it is dropped in the mouth.



NOTE: Unscrew the screw counterclockwise.



## **5.** CATALOGUE PAGES

## **5a.** INSTRUMENT SET

#### ChMP Instrument set - 3.4499

40.8409.000

	Name	Catalogue No.	Pcs
	Quick coupling handle	40.6405.100	1
<b>€</b>	Screwdriver tip X	40.6449.023	1
= =====================================	Screwdriver tip X	40.6449.083	1
	Drill 1.6/8	40.6422.600	1
×1700	Drill 1.6/8	40.6422.608	1
	Dissecting forceps STANDARD 14.5cm	30.3303.000	1
	Flat wrench	40.8402.100	1
la D	Trial 3.4499.017	43.4499.017	1
	Trial 3.4499.020	43.4499.020	1
(m 2)	Trial 3.4499.023	43.4499.023	1
(max)	Trial 3.4499.026	43.4499.026	1



Stand **40.8403.000** 



\* Additionally Available

	Name	Catalogue No. Pcs
100.2	Trial 3.4499.029	43.4499.029 <b>*</b>
ON D	Trial 3.4499.032	43.4499.032 <b>*</b>
[m5]	Trial 3.4499.035	43.4499.035 <b>*</b>



## **5b.** IMPLANTS







## **Transpalatal distractor**

distraction	(Len)	(TiA)
8	17	3.4499.017
13,5	20	3.4499.020
19	23	3.4499.023
24	26	3.4499.026

17 <b>*</b>	22	3.4499.022
20,5*	24	3.4499.024
29,5*	29	3.4499.029
34,5 <b>*</b>	32	3.4499.032
40 <b>*</b>	35	3.4499.035

<sup>\*</sup> Additionally Available









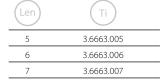






## **Self-drilling microscrew 2.0**







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