MANUAL EN

LASAK

# Fully guided surgery for an edentulous jaw

Easy and effective

BioniQ

## Preface

This manual is intended for dental professionals and contains basic information, working procedures and recommendations for treating edentulous jaws with BioniQ implants inserted at the level of the bone with BioniQ fully guided surgery. To master this advanced treatment method safely, it is recommended that dental professionals completely familiarise themselves with BioniQ's general fully guided surgical procedures, which can be found in a separate manual.


## Disclaimer

Please be aware that general knowledge of BioniQ's fully guided surgery procedures, general knowledge of dental implantology and familiarity with working with BioniQ's implantology system are essential for using BioniQ fully guided surgery to treat edentulous jaws; in addition to the information in this manual.

Pre-operative procedures (therapeutic intent, CT scans, the planned implant positions and working with a planning program, designing and producing the surgical template and temporary prostheses etc.) and post-operative procedures are not covered in this manual. Before using BioniQ fully guided surgery products and services, carefully read the Terms and Conditions of Use of LASAK guided surgery, which are available on www.lasak.com. By using BioniQ fully guided surgery products and services, you accept the Terms and Conditions of Use of LASAK guided surgery . If you do not accept these Conditions, do not use BioniQ fully guided surgery products or services.

Please, note that not all products and services described in this document may be available in all countries.

Easy and effective

Contents

# Introduction

BioniQ fully guided surgery also allows the management of prostheses for individual treatment of edentulous and partially edentulous jaws. This advanced solution allows the surgical template to be precisely anchored even in the most challenging anatomical conditions. The reference pin for guided surgery plus accessories will ensure that the surgical template remains in a stable position during the entire surgical procedure, thus allowing the dental implants to be inserted safely and accurately into the planned location.

**For maximum accuracy, the treatment uses two surgical templates, one for each phase of treatment, as shown in the diagram below.**

## 1. Surgical template

Preparing bone beds for reference pins

## 2. Surgical template

Treatment with dental implants

## WORKING PROCEDURE DIAGRAM

**PHASE 1**

- Therapeutic intention
- CT scan A Jawbone surface image A
- Planning the placement of reference pins
- Designing and producing the first surgical template
- Inserting the reference pins
- Using vertical fixation pins
- CT scan B Jawbone surface image B
- Removing vertical fixation pins
- Inserting cover screws

**PHASE 2**

- Designing the placement of guide sleeves for vertical fixation pins
- Planning the placement of implants
- Designing and producing the second surgical template
- Designing and producing temporary prostheses
- Surgical and prosthetic treatment

## The reference pin

The stability of the surgical template is essential if the surgical treatment is to be accurate from start to finish. This is particularly important when placing the template on the gingiva of an edentulous jaw, as this is where the greatest inaccuracies may occur. Reference pins for guided surgery are inserted into the jaw to create a firm anchor. The position of the pins is recorded by CT scan B in the first treatment phase. The second surgical template is fixed to the reference pin in the second treatment phase.

| Product | Ref. No. |
|---|---|
| Reference pin for guided surgery, QN/L7/d2.9/C4.6 (GS) | 2536.00 |

The reference pin is inserted manually, using the carrier included with the reference pin packaging, or using a QN Direct driver for guided surgery (Ref. No. 2530 00). The reference pin for guided surgery is designed to be inserted into the bone for no longer than 30 days. The carrier and cover screw are part of the reference pin packaging. The carrier is attached in case the reference pin is inserted with a driver/ Unigrip and ratchet. The cover screw protects the reference pin in the time between the first and second phases of the procedure. The reference pin for guided surgery is supplied non-sterile, packed in a sterilisation pouch.

## The guided drill and sleeve for guided surgery

To prepare a bed for the reference pin for guided surgery, use a pin drill (Ref. No. 2527 00) with a diameter of 1.3mm guided by a Steco guide sleeve (Ref. No. M.27.24.D130L5). To prepare the bed accurately, navigate using the first surgical template.


| Product | Ref. No. |
|---|---|
| Guided drill for pin, d1.3 (GS) | 2527.00 |
| Steco sleeve – with depth stop for pin drill, d1.3 (GS) | M.27.24.D130L5 |

## The fixation pin

Fixation pins are used to accurately record the position of the inserted reference pins during the CT/CBCT scan of the jaw in the first treatment phase and to secure the second surgical template in the second treatment phase. The fixation pin is screwed into the inserted reference pin through the Steco sleeve (Ref. No. M.27.15. D350).


| Product | Ref. No. |
|---|---|
| Guided fixation pin – vertical, QN/H8/d3.5 (GS) | 2535.08 |
| Steco sleeve – with depth stop for vertical fixation pin, d3.5 (GS) | M.27.15.D350 |

The vertical fixation pin for guided surgery (Ref. No. 2535.08) is primarily designed for use with the reference pin for guided surgery (Ref. No. 2536.00). The fixation pin's outer guide diameter of 3.5mm minimises the space required. A Steco sleeve with depth stop for the d3.50 vertical fixation pin (Ref. No. M.27.15.D350), is used for this vertical fixation pin.
If the anatomical and spatial conditions allow the vertical fixation pins for the QN yellow prosthetic platform (Ref. No. 2523.06, 2523.08 and 2523.10) may be used. For these vertical fixation pins, which have an outer guide diameter of 5.2mm, we select a Steco sleeve with a depth stop for fully guided surgery, d5.20 (Ref. No. M.27.15.D520).

## CAD libraries

Most general planning software may be used to plan BioniQ fully guided surgery. A list of this software, and a current library, are available for download from www.lasak.com. If anything is unclear, or in case of problems with the library, please email us at cadcam@lasak.cz.

# The principle behind the working procedure

Placing the template on the gingiva risks inaccuracies during treatment of the edentulous jaw. Ensuring the exact position of the planned implants is key to the success and predictability of prosthetic treatment. The reference pins inserted into the patient's jaw create stable points for planning and fixing the second surgical template.

## PHASE I

In the first phase of the procedure, the beds of the reference pins for guided surgery are prepared using the first surgical template. The reference pins are then inserted into the bone without the template. The vertical fixation pins are screwed into the inserted reference pins. When the components are assembled in this way, a CT scan is done and/or jawbone surface image is made to establish the exact position of the reference pins and subsequently planned dental implants, as well as the position of the second surgical template. Then the vertical fixation pins are removed, and the inserted reference pins are closed with the cover screws.

### Scanning

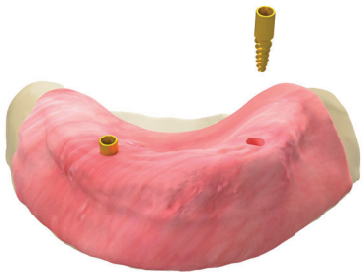
CT
Intra-oral /extra-oral scanning

### Planning

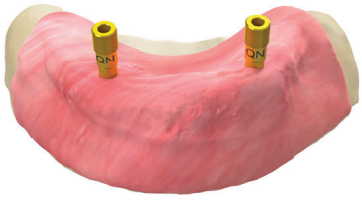
Plan the placement of reference pins
Design and make the first surgical template

### Prepare the reference pin bed

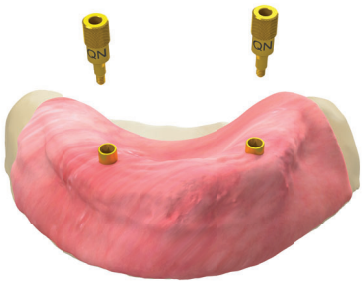
### Insert the reference pins



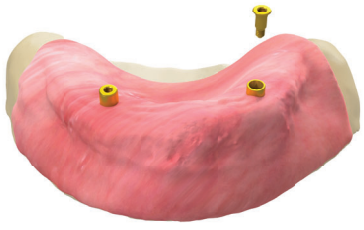
### CT scan the screwed-in fixation pins



### Unscrew the vertical fixation pins



### Insert the cover screws



**Planning the placement of the reference pins and designing and producing the first surgical template must precede the above steps. When planning the placement of reference pins, and depending on the planning software used, a CT scan and/or jawbone surface image is needed. This will allow the position of the reference pins and surgical template to be designed safely.**

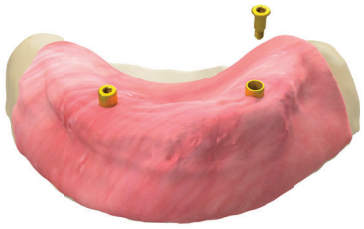
## PHASE 2

In the second phase of the procedure, planning is required for the position of the dental implants, guide sleeves for the dental implants, guide sleeves for the vertical fixation pins or guide sleeves for the additional horizontal fixation pins if they are to be used (more on p. 17); the second surgical template is also designed, which will be used for implant insertion.
During the surgical treatment itself, the cover screws should first be removed from the reference pins, then the second surgical template put in place and anchored by screwing the vertical fixation pins into the reference pins. Next, the implant beds should be prepared, and the implants inserted using the techniques of BioniQ fully guided surgery. Then the vertical fixation pins should be unscrewed, and the second surgical template removed. The final step is covering the dental implants with the appropriate cover screws or gingiva formers or possibly using temporary restoration.

**Planning**

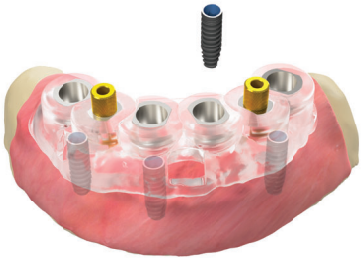
Planning the placement of implants
Design and make the second surgical template

**Remove the cover screws from the reference pins**

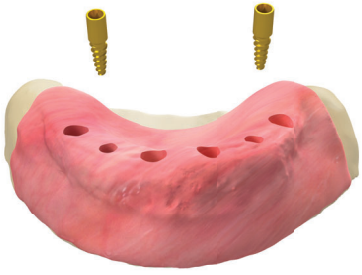


**Place the second surgical template, fix the template to the reference pins**

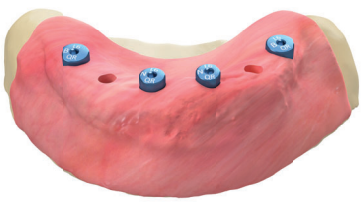
**Insert the implants**



**Extract the reference pins**



**Position the cover screws or gingiva formers**



# The working procedure step by step

The following pages describe situations using BioniQ S3.5/L10 implants and two QN/L7/d2.9/C4.6 (GS) reference pins for guided surgery as examples of working and surgical procedures. The use of additional horizontal fixation pins is not illustrated. The example shows a surgical template on the gingiva of an edentulous jaw using flapless techniques.

## PHASE I

### 1) CT scan, jawbone surface image

Conduct the CT/CBCT scan of the jawbone ("CT scan A"). When doing so, observe the tried-and-tested procedures of good clinical practice, the scanner device manufacturer's instructions, and the precautions below to obtain high-quality CT data.
Some planning software requires another set of input data, jawbone surface images likewise. Depending on the requirements of the planning software, make an extra-oral jawbone surface image (impression – model – scan of the model), or use an intra-oral scanning method ("jawbone surface image A").

***Precautions***

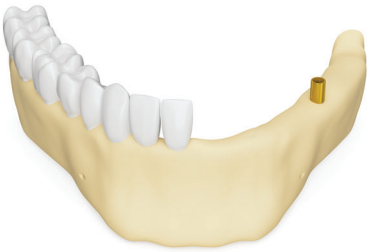
- *The CT data should be in DICOM format with a cross-section density of no more than 0.5mm, ideally 0.3mm.*
- *The field of view of the jawbone should be large enough to allow easy diagnostic evaluation of the clinical situation and provide sufficient information to enable reliable alignment with the jawbone surface image.*
- *The diagnostic quality of the image must be good enough to allow the imaging data to be accurately assessed.*
- *Do not do a CT/CBCT scan with the teeth occluded.*
- *Stabilise the mandible in relation to the maxilla by instructing the patient to gently bite into a bite separator such as a bite pad or cotton-wool pad.*
- *Any unspecified metal parts in both jaws (e.g., prostheses) should be removed before the CBCT imaging unless necessary for diagnostic reasons. This will prevent potential mistakes.*
- *If the patient moves during the CBCT imaging, motion artifacts will appear, and a discontinuity in the anatomy or a double anatomical boundary will be shown on the image. This will reduce the quality of the imaging data and will hamper the CBCT-jawbone surface image alignment process or even make it impossible.*
- *The forms and anatomy of any tooth restored using metal, or ceramic materials will not be clearly reproduced during a CT scan due to metal artifacts. If metal artifacts clearly impair such teeth and any adjacent teeth, they should not be used in the alignment process.*
- *High-quality scans must be used for the alignment process, or they will not be usable as the basis for the planned implant procedure.*
- *The doctor is responsible for generating CT/CBCT scans at the optimum quality using the lowest possible radiation dose.*
- *The patient should always be positioned and scanned in accordance with the instructions provided by the scanning device manufacturer.*

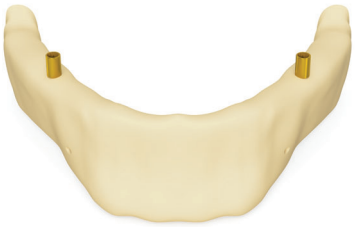
## 2) Planning the placement of reference pins

Using planning software, plan the position of the QN/L7/d2.9/C4.6 (GS) reference pins for guided surgery, Ref. No. 2536.00.
**When planning the reference pins, follow the recommendations below:**

- **Always consider the number of reference pins in terms of the specific anatomical situation. The number of reference pins used may affect the accuracy of the work and the stability of the surgical template.**

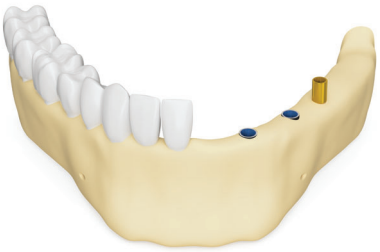
The number of planned reference pins depends on the number of teeth in the jaw. For partially edentulous jaws, a single reference pin may be sufficient. Using at least two reference pins is appropriate if the jaw is completely edentulous. Select only the necessary number of pins to secure the template.





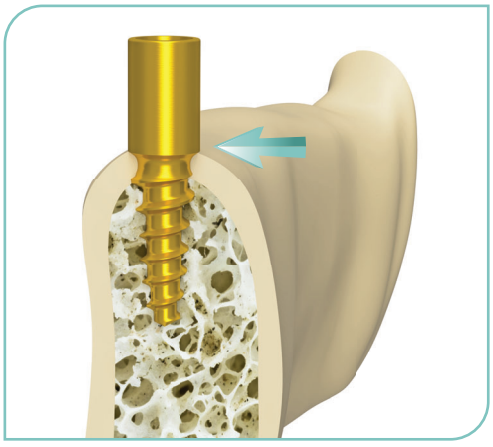
- **When planning the distribution of reference pins, always consider the position of the intended dental implants.**

Ensure that the reference pins are sufficiently distanced from the dental implants,. Also, remember that for each reference pin and implant, a specific size of guide sleeve must be inserted into the surgical template. In addition, the individual guide sleeves must be sufficiently far apart to maintain the surgical template's stability.



- **Carefully consider the incline and depth of insertion of the reference pins.**

The reference pin neck should be positioned above bone level, with the transition between the neck and the screw part of the reference pin at bone level. The stop on the reference pin functions as a depth stop when inserted into the bone.

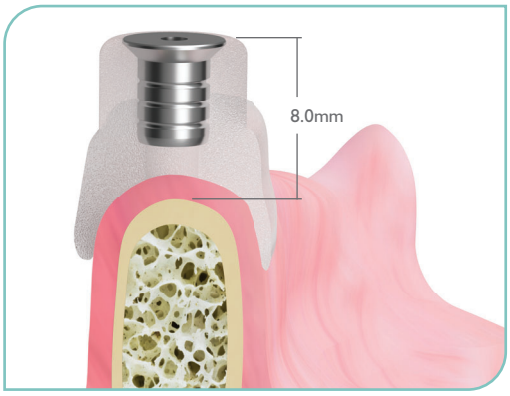


- Reference pins must be positioned in a sufficient volume of cortical bone.
- When planning, the patient's ability to open the mouth must be considered. It is essential to maintain easy access for handling the pins.

# The working procedure step by step

## 3) Designing the first surgical template

In the planning software, design the first surgical template, which will guide the drill when preparing the reference pin bed so that the pins can be accurately inserted into their planned positions.




- In the surgical template, design a Steco guide sleeve for each reference pin, with a d1.3 (GS) drill stop for the pin.
- The upper surface of the guide sleeve must be 8mm from the bone level (i.e., offset H8).

| Product | Ref. No. | Inner sleeve diameter | Sleeve height |
|---|---|---|---|
| Steco sleeve – with depth stop for drill for pin, d1.3 (GS) | M.27.24.D130L5 | Ø 1.3mm | 5.0mm |

## 4) Positioning the first surgical template

When preparing the reference pin bed, use the first **surgical template.**

- Place the first surgical template on the gingiva.
- Check that the template fits correctly and is stable enough for further work.

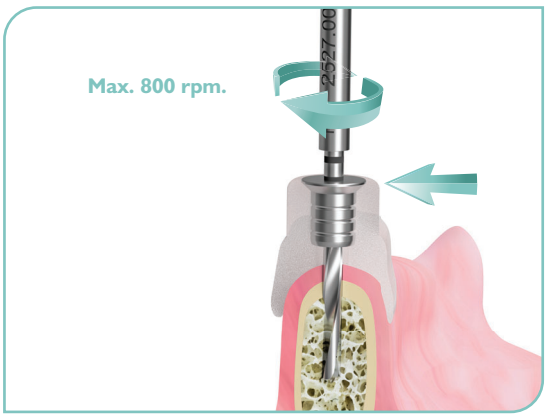
***Note***

***Any digital interference from the reference pin and guide sleeve in the planning software is neither an error nor a reason to worry. The Steco guide sleeve – with pin drill stop, d1.3 (GS) – and the reference pin for guided surgery, QN/L7/d2.9/C4.6 (GS), will not, in fact, come into contact. This guide sleeve is used only to prepare the reference pin bed. The surgical template is then removed, and the reference pin is inserted without it.***

## 5) Prepare the reference pin bed

The reference pin bed for guided surgery, QN/L7/d2.9/C4.6 (GS), is prepared with a guided drill for pin, d1.3 (GS).


| Instrument | Ref. No. | Diameter | Effective length |
|---|---|---|---|
| Guided drill for pin, d1.3 (GS) | 2527.00 | Ø 1.3mm | 18.5mm |




Insert the guided drill for pin, d1.3 (GS), into the guide sleeve in the surgical template.

- Drill through the gingiva up to about half the length of the drill.
- Remove the drilled bone fragments by retracting the drill back.

After reaching the required preparation depth, drill to the first laser mark from the tip of the drill.

**The maximum drill speed is 800 rpm.**

***Caution***

- *During preparation, cool the drill externally with plenty of cold, sterile saline.*
- *The drill must not turn when it is being inserted into the guide sleeve.*
- *The drill must move freely through the guide sleeve.*
- *Avoid lateral pressure on the drill.*
- *Drill intermittently.*

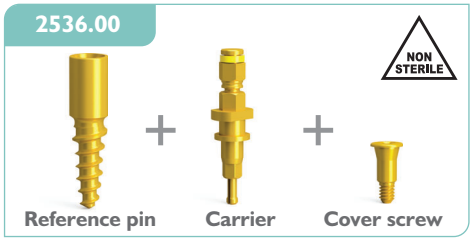
## 6) Insert the reference pins

The reference pins for guided surgery, QN/L7/d2.9/C4.6 (GS), may be inserted: a) manually, using the supplied carrier and a BioniQ Unigrip and ratchet, b) mechanically, using a Direct driver (GS) and a surgical unit. The primary method for inserting reference pins for guided surgery is a carrier with a Unigrip and ratchet.

**The maximum recommended insertion torque for a reference pin for guided surgery is 60 Ncm.**

### 6a) Inserting reference pins using a carrier and Unigrip

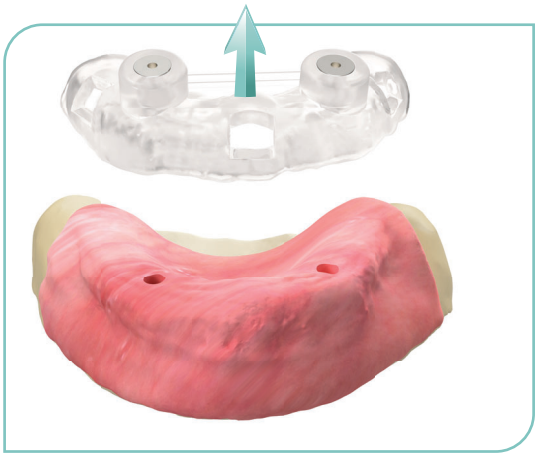
The reference pin for guided surgery is supplied non-sterile, packed in a sterilisation pouch. The carrier and cover screw are part of the packaging. The reference pin, carrier and cover screw must be sterilised before use. You can find more information about the sterilisation procedure in the Cleaning and sterilisation section (p. 23).




Unigrip allows the reference pin to be safely inserted into the prepared bone bed using a carrier. The Unigrip and ratchet are part of the surgical instrument set for BioniQ guided surgery.

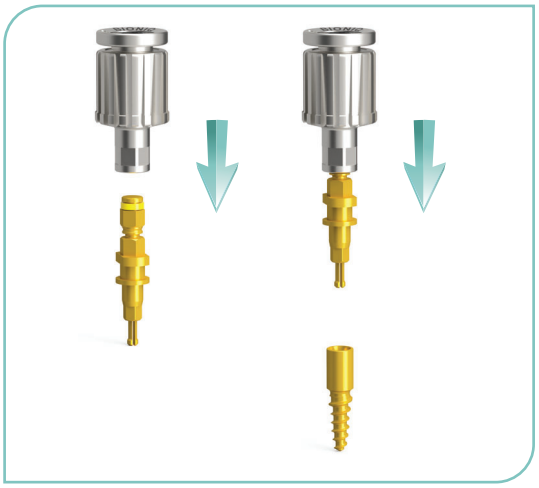

| Instrument | Ref. No. |
|---|---|
| Unigrip, hex 2.5/ISO/L16 | 2459.00 |
| Ratchet | 2408.00 |

# The working procedure step by step



- Remove **the first surgical template**, which was used to prepare the reference pin bed.

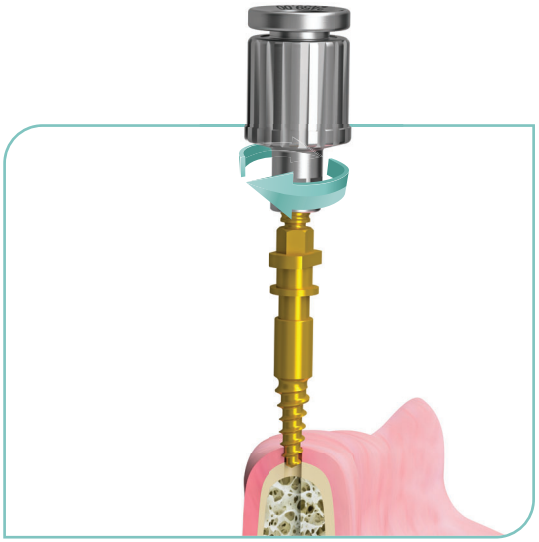
The reference pins are inserted without the surgical template in place.



The reference pin for guided surgery and carrier are packaged separately, each in its sterilisation pouch. Before use, these components must be sterilised and correctly assembled.

- Using the Unigrip, remove the carrier from the sterilisation pouch.
- Use the Unigrip to slide the carrier into the reference pin.

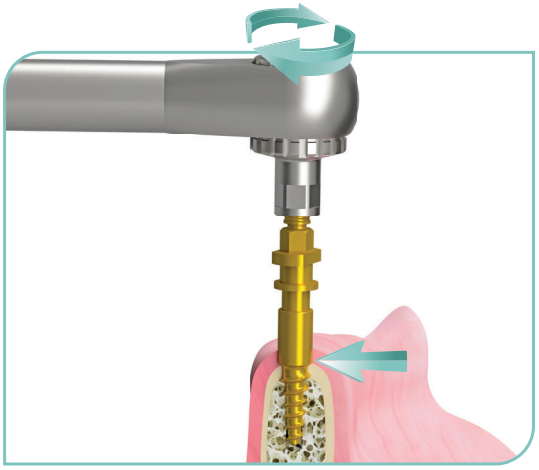
The reference pin is now ready for insertion.



Start the insertion manually without using the ratchet.

- With the Unigrip, insert the reference pin into the top of the prepared bed.
- By turning slowly clockwise, screw in the reference pin deeply enough for it to be sufficiently stable and allow the use of the ratchet.

**Ensure the instrument is correctly guided along the axis of the prepared bone bed.**



Use the BioniQ ratchet to insert the reference pin into the planned position with the correct insertion torque.

- During insertion, turn the ratchet using the torque adapter spring end only.
- The lower edge of the reference pin neck should reach bone level.

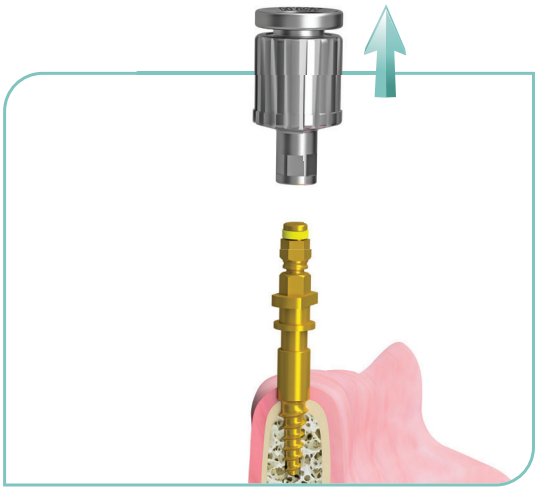
**It is essential that the pin is retained sufficiently in the bone.**

**The maximum recommended insertion torque of reference pins for BioniQ guided surgery is 60 Ncm. However, if sufficient retention is achieved at a lower torque, there is no need to tighten to the maximum torque of 60 Ncm.**

***Caution***

*If the recommended insertion torque of 60 Ncm is exceeded, this may damage the bone bed, and the bone may lose its ability to retain the inserted reference pin. In this case, the reference pin must be removed and placed in another location if required. The unused reference pin bed must be treated appropriately.*

*If the recommended insertion torque of 60 Ncm is exceeded, the ratchet's torque adapter and the reference pin's internal geometry may be damaged, or the carrier may be trapped in the reference pin. If a torque of 90 Ncm is exceeded, the upper part of the carrier will break off as a safety feature. You can find more information in the BioniQ Safe implant carrier leaflet.*

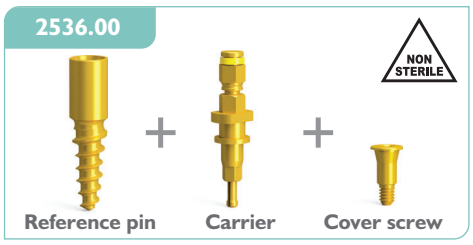


- Pull the Unigrip out of the carrier.
- Pull the carrier out of the reference pin.

**Be very careful to avoid dislocating the reference pin when releasing the carrier.**

## 6b) Inserting the reference pin using a Direct driver

The reference pin for guided surgery is supplied non-sterile, packed in a sterilisation pouch. The carrier and cover screw are part of the packaging. The reference pin, carrier and cover screw must be sterilised before use. You can find more information about the sterilisation procedure in the Cleaning and sterilisation section (p. 23).

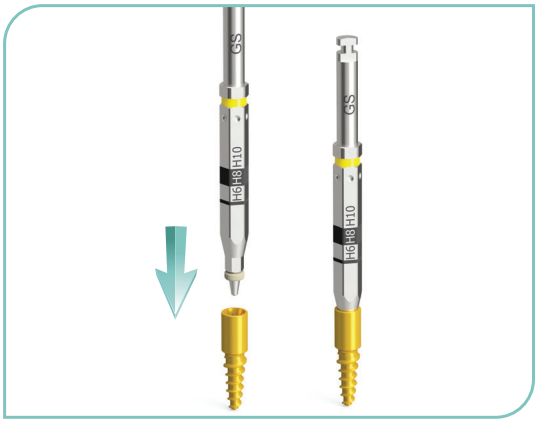



The QN Direct mechanical driver (GS) is designed for inserting a reference pin for guided surgery using a surgical unit. Using a carrier and Unigrip is the primary recommended method for inserting a reference pin.


| Instrument | Ref. No. |
|---|---|
| Direct Driver QN – mechanical, QN/ISO/L18 (GS) | 2530.00 |

# The working procedure step by step

Remove **the first surgical template**, which was used to prepare the reference pin bed.
The reference pins are inserted without the surgical template in place.




The reference pin for guided surgery is supplied in a sterilisation pouch and must be sterilised before use.

- Slide the QN Direct driver into the reference pin and remove the pin from the sterilisation pouch.

The reference pin is now ready for insertion.


- Insert the Direct (QN) driver with the attached reference pin into the prepared bed. The axes of the driver-reference pin set should align with the axis of the bed.
- Insert the reference pin into the planned position with the speed of the surgical drill set to slow.
- The lower edge of the reference pin neck should reach bone level.

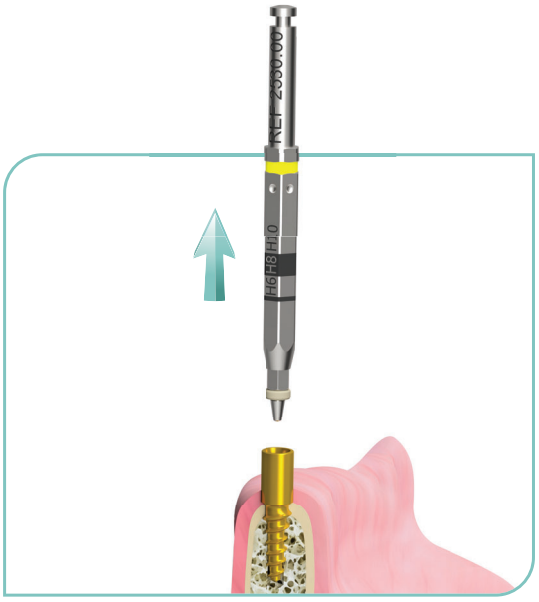
**Do not exceed 20 rpm.**

**It is essential that the pin is retained sufficiently in the bone.**

**The maximum recommended insertion torque of reference pins for guided surgery is 60 Ncm. However, if sufficient retention is achieved at a lower torque, there is no need to tighten to the maximum torque of 60 Ncm.**

***Caution***

*If the recommended insertion torque of 60 Ncm is exceeded, this may damage the bone thread, and the bone may lose its ability to hold the inserted reference pin. In this case, the reference pin must be removed and placed in another location if required. The unused reference pin bed must be treated appropriately.*
*If the recommended insertion torque of 60 Ncm is exceeded, this may also damage the driver or inner geometry of the reference pin.*



- Pull the Direct (QN) driver out of the reference pin.

**Be very careful to avoid dislocating the reference pin.**

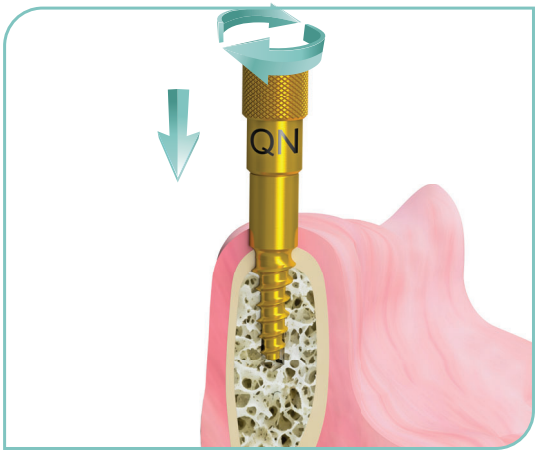
## 7) Using vertical fixation pins

Vertical fixation pins, which are screwed into the reference pins in this phase for the scanning step, will be used in the second phase of the procedure to ensure the stability of the second surgical template. When choosing the size of vertical fixation pins, carefully consider the space requirements of the planned vertical fixation pins and relevant guide sleeves in the second surgical template. The individual guide sleeves must be sufficiently far apart to maintain the surgical template's stability.

The vertical fixation pin for guided surgery (Ref. No. 2535.08) is primarily designed for use with the reference pin QN/H8/d3.5 (GS) for guided surgery, Ref. No. 2535.08. The fixation pin's outer guide diameter of 3.5mm minimises the space required. If a specific case requires a different choice of size, an alternative choice may be made from the selection of vertical fixation pins in the QN yellow prosthetic platform.


| Product | Ref. No. | Outer diameter | Height |
|---|---|---|---|
| Guided fixation pin – vertical, QN/H8/d3.5 (GS)* | 2535.08 | Ø 3.5mm | 12.8mm |
| Guided fixation pin – vertical, QN/H6/d5.2 (GS) | 2523.06 | Ø 5.2mm | 15.4mm |
| Guided fixation pin – vertical, QN/H8/d5.2 (GS) | 2523.08 | Ø 5.2mm | 17.4mm |
| Guided fixation pin – vertical, QN/H10/d5.2 (GS) | 2523.10 | Ø 5.2mm | 19.4mm |

* Primary fixation pin designed for use with the reference pin for guided surgery (GS)



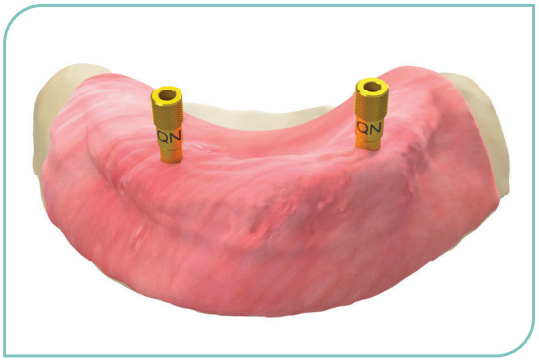

- Screw the vertical fixation pin into the inserted reference pin up to the stop.
- Tighten it by hand or with a screwdriver.

**Be very careful to avoid dislocating the reference pin when screwing.**

**Do not exceed the tightening torque of 5-10 Ncm.**

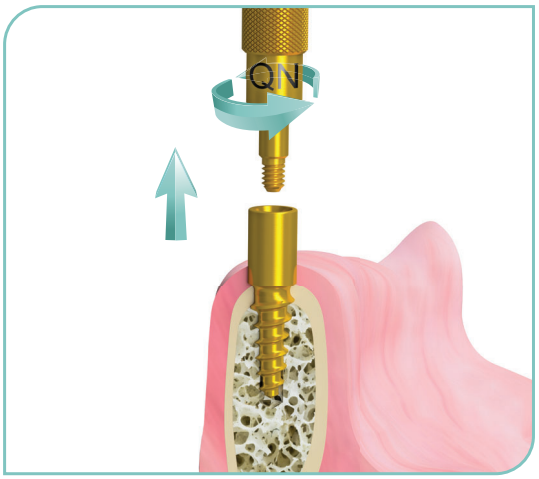
# The working procedure step by step

## 8) CT scan, jawbone surface image




Conduct CT/CBCT scan B of the jawbone (“CT scan B”), which will record the exact positions of the inserted reference pins and vertical fixation pins. When doing so, observe the tried-and-tested procedures of good clinical practice, the scanner device manufacturer’s instructions and the precautions in step 1 (see p.8) to obtain high-quality CT data.
Some planning software requires another set of input data, jawbone surface images likewise. Depending on the requirements of the planning software, make an extra-oral jawbone surface image (impression – model – scan of the model), or use an intra-oral scanning method (“jawbone surface image B”).

## 9) Removing vertical fixation pins




- Unscrew the vertical fixation pin from the inserted reference pin.

**Be very careful to avoid dislocating the reference pin.**

## 10) Inserting cover screws

The cover screw protects the inserted reference pin in the period between the first and second phases of the procedure. The cover screw for the QN yellow prosthetic platform is included in the packaging of the reference pin for guided surgery. The cover screw can be ordered separately using Ref. No. 2164 00.
The cover screw is supplied **non-sterile** and packed in a sterilisation pouch. The cover screw must be sterilised before use. You can find more information about the sterilisation procedure in the Cleaning and Sterilisation section (p. 23).

- Screw the cover screw into the inserted reference pin and tighten it with a manual screwdriver.

To avoid dislocating the reference pin, the cover screws must be screwed in with great care.

**Do not exceed the tightening torque of 5-10 Ncm.**

The reference pin for guided surgery is designed to be **inserted into the bone for a limited period not exceeding 30 days.**

## 11) Designing guide sleeves for vertical fixation pins

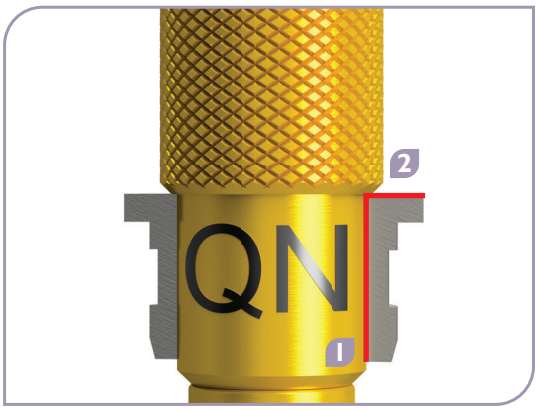
Using CT scan B and/or jawbone surface image B in the planning software, plan the positions of the guide sleeves for the vertical fixation pins.

The vertical fixation pin for guided surgery, QN/H8/d3.5 (GS), Ref. No. 2535.08, is primarily designed for use with the reference pin for guided surgery (Ref. No. 2536.00). If a specific case requires a different size, a choice may be made from the selection of vertical fixation pins in the QN yellow prosthetic platform.

**When designing guide sleeves for vertical fixation pins, follow the recommendations below:**

When choosing guide sleeves, observe the diameters of the vertical fixation pins used. For vertical fixation pins with the specification d3.5, select the Steco sleeve with depth stop for the vertical fixation pin, d3.50 (GS). For vertical fixation pins with the specification d5.2, select the Steco sleeve with depth stop for fully guided surgery, d5.20 (GS).

| Product | Ref. No. | Inner diameter | Sleeve height | Vertical fixation pin |
|---|---|---|---|---|
| Steco sleeve – with depth stop for vertical fixation pin, d3.5 (GS) | M.27.15.D350 | Ø 3.5mm | 3.0mm | 2535.08 |
| Steco sleeve – with depth stop for fully guided surgery, d5.20 (GS) | M.27.15.D520 | Ø 5.2mm | 4.0mm | 2523.06<br>2523.08<br>2523.10 |




The position of the planned guide sleeve must exactly match the recorded position of the vertical fixation pin.

- The inner cylinder surface of the guide sleeve must be in contact with the outer contact cylinder surface of the vertical fixation pin 1.
- The outer stop surface of the guide sleeve must be in contact with the surface of the vertical fixation pin stop 2.

**Compliance with the described rules is essential when designing guide sleeves for vertical fixation pins to ensure that the component set – reference pin, vertical fixation pin, guide sleeve – functions correctly.**

## Designing guide sleeves for additional horizontal fixation pins (optional)

For edentulous jaws, it is appropriate to select at least one horizontal fixation pin for guided surgery along with the reference pins to fix the second surgical template. When selecting this step in the planning software, plan the positions of guide sleeves for horizontal fixation pins. The horizontal fixation pin will secure the surgical template against "axial" motion. For example, pressing the template down onto the soft tissue, or lifting the template with the tongue, may constitute adverse movements of this sort.

The same guided drill (Ref. No. 2527 00) and guide sleeve (Ref. No. M.27.24.D130L5) are used for the horizontal fixation pin and for preparing the reference pin bed.


| Instrument | Ref. No. | Diameter | Effective length |
|---|---|---|---|
| Guided drill for pin, d1.3 (GS) | 2527.00 | Ø 1.3mm | 18.5mm |
| Guided fixation pin – horizontal, d1.3/L25/L17 (GS) | 2526.00 | Ø 1.3mm | 17mm |

| Product | Ref. No. | Inner diameter | Sleeve height |
|---|---|---|---|
| Steco sleeve – with depth stop for drill for pin, d1.3 (GS) | M.27.24.D130L5 | Ø 1.3mm | 5.0mm |

# The working procedure step by step

## 12) Planning the placement of implants

Use the planning software to plan the positions of the intended dental implants, keeping the tried-and-tested principles of good clinical practice in mind.

## 13) Designing the second surgical template

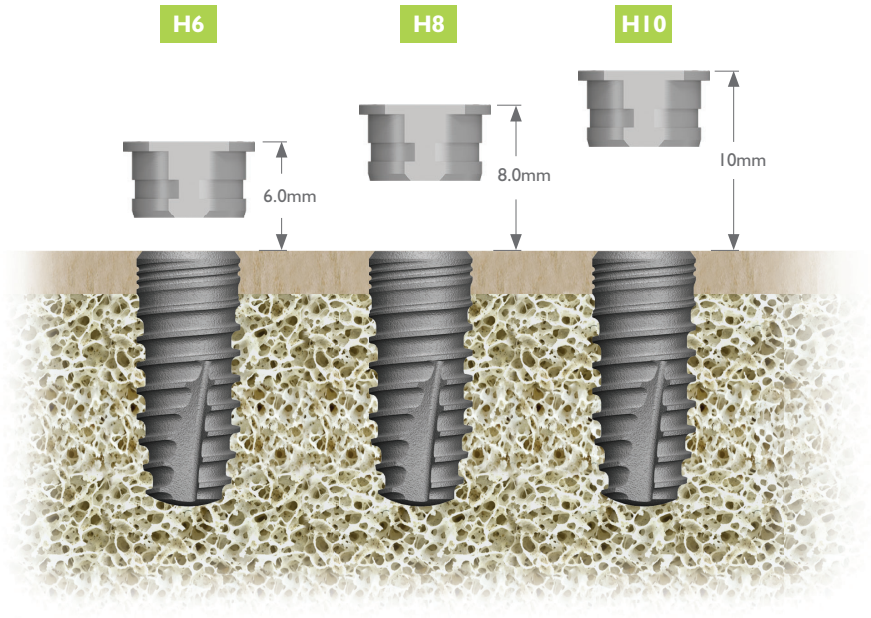
In the planning software, design the second surgical template, the purpose of which is to guide the dental implants accurately into their planned positions.

For each BioniQ dental implant, design a Steco guide sleeve with depth stop for fully guided surgery, d5.20 (GS), in the surgical template.

| Product | Ref. No. | Outer diameter | Sleeve height |
|---|---|---|---|
| Steco sleeve – with depth stop for fully guided surgery, d5.20 (GS) | M.27.15.D520 | Ø 5.2mm | 4.0mm |

## The position of the guide sleeves

During BioniQ fully guided surgery, the guide sleeves may be placed into three positions at different distances (called offsets) from bone level. These positions are called H6, H8 and H10, and they correspond to the length of the upper edge of the sleeve from the bone level in millimetres, i.e., 6mm, 8mm or 10mm. The position of the guide sleeve in the template is set while the template is being planned.




**When choosing the optimum position for the guide sleeve, follow the recommendations below:**

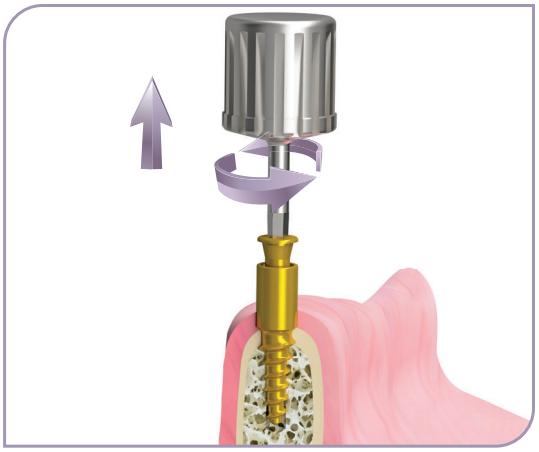
- Place the guide sleeve as close to the bone or soft tissues as anatomical conditions permit.
- Under no circumstances should the guide sleeve come into contact with the soft tissues.
- Sufficient space must be maintained for cooling the instruments.

**Recommendations**

**If your planning software allows, extract digital data from the vertical fixation pins. In this way, you will prevent the vertical fixation pin elements from potentially interfering with the general elements of the surgical template.**

## 14) Removing cover screws

The first step in the second phase of the surgical procedure is to remove the cover screws placed in the inserted reference pins for guided surgery.



- Unscrew the screws from the reference pins manually with a screwdriver.

**Be very careful to avoid dislocating the reference pin.**

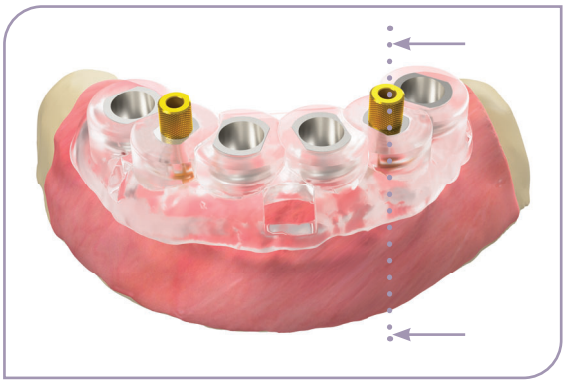
## 15) Positioning the second surgical template

For guided implant insertion, use the **second surgical template**, which will ensure that the instruments are guided accurately, and the implant is safely positioned into the previously planned location.

- Place the first surgical template on the gingiva.
- Check that the template fits correctly and is stable enough for further work.

## 16) Using vertical fixation pins

Vertical fixation pins are used to ensure the stability of the surgical template during the procedure. Vertical **fixation pins are screwed into the reference pins** inserted in **the first treatment phase**. The reference pins create stable, defined points in the patient's jaw, which ensures the exact position of the surgical template.
Use the vertical fixation pins that correspond to the guide sleeves and their vertical positions as planned and used.




- Screw the vertical fixation pin into the inserted reference pin.
- Tighten vertical fixation pins for guided surgery manually or with a manual screwdriver.

**Be very careful to avoid dislocating the reference pin when screwing.**

**Do not exceed the tightening torque of 5-10 Ncm.**

# The working procedure step by step

## Using additional horizontal fixation pins (if the template has guide sleeves for them)

The horizontal fixation pin will secure the surgical template against “axial” motion. For example, pressing the template down onto the soft tissue, or lifting the template with the tongue, may constitute adverse movements of this sort. The horizontal fixation pin is inserted through the gingiva and held in place by surface friction.
The same guided drill (Ref. No. 2527.00) is used for the horizontal fixation pin as for preparing the reference pin bed.


| Instrument | Ref. No. | Diameter | Effective length |
|---|---|---|---|
| Guided drill for pin, d1.3 (GS) | 2527.00 | Ø 1.3mm | 18.5mm |
| Guided fixation pin – horizontal, d1.3/L25/L17 (GS) | 2526.00 | Ø 1.3mm | 17mm |

You can find more information about fixing the surgical template using horizontal fixation pins in the separate document **Fully guided surgery**. Knowledge of this is an essential prerequisite for using BioniQ fully guided surgery to treat an edentulous jaw.

**Fully guided surgery**

## 17) Surgical treatment

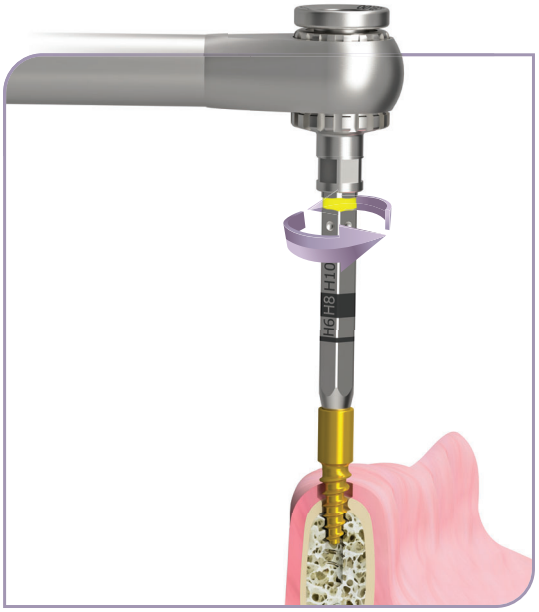
The surgical template is now fixed in the planned position and ready for the surgical treatment and the insertion of the dental implants into the planned locations.
The surgical procedure is described in the separate document **Fully guided surgery**. Knowledge of this is an essential prerequisite for using BioniQ fully guided surgery to treat an edentulous jaw.

**Fully guided surgery**

## 18) Removing reference pins

After all planned dental implants have been inserted, the inserted reference pins for guided surgery must be removed from the patient’s jaw.

- Unscrew all vertical fixation pins from the reference pins manually or using a manual screwdriver.
- Remove the second surgical template.



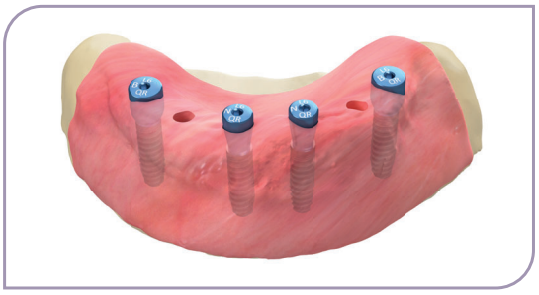
Use the QN Direct driver (Ref. No. 2530.00) with the Unigrip and BioniQ ratchet to remove the reference pins.

- Attach the Unigrip to the Direct driver.
- Slide the Direct driver into the reference pin and attach the ratchet to the Unigrip.
- Turn the ratchet anti-clockwise to unscrew the reference pin from the patient's jaw.

**Ensure that the instrument is correctly guided in the axis of the reference pin.**

## 19) Covering

Cover the inserted dental implants with the cover screws or gingiva formers, depending on the specific surgery plan. If the implants are sufficiently stable and meet all other prerequisites for this method, it is possible to proceed to immediate load.



The gingiva former should exceed the margin of the adapted soft tissue by 1.0 to 2.0mm to prevent it from being covered by the edematous tissue during the post-operative period.
The diameter of the gingiva former should be as close as possible to the diameter of the abutment of the future prosthesis.

**Wounds left by the removal of the reference pins must be treated appropriately.**

## MAINTENANCE

The quality and lifespan of instruments depend on adherence to prescribed care and maintenance. Instruments must be cleaned and disinfected immediately after use. Organic residues must not be allowed to dry on the instruments. Use only cleaning and disinfecting agents recommended for surgical instruments (such as DENTACLEAN Instrument Plus). Agents with a high chlorine content and agents containing oxalic acid or hydrogen peroxide are not suitable for cleaning and disinfecting stainless steel and anodised titanium products. Likewise, preparations with a low or high pH may damage the instrument surface. Always use cleaning and disinfecting agents according to the manufacturer's instructions (concentration, time, temperature, solution expiry date and instrument exposure). When cleaning and disinfecting, always use appropriate personal protective equipment.

Clean the surface of the instruments mechanically using a brush with nylon bristles (wire brushes may damage the instrument's surface) and then in an ultrasonic bath, where it is essential to ensure that the instruments do not touch each other (using suitable organisers). Special attention must be paid to any openings and cavities (a miniature brush, such as an interdental brush, is suitable for cleaning). More complex instruments (e.g., ratchets) must be dismantled before cleaning. Saline, disinfectant or cleaning agent residues must be thoroughly rinsed off in running water, and the instrument must then be dried. Instruments must also be dried without coming into contact with each other. When drying, do not exceed a temperature of 120°C (too high a temperature may damage the instruments).

The recommended method for cleaning and disinfecting LASAK instruments (as validated by LASAK). First, disinfect the instruments in an immersion bath in the detergent DENTACLEAN Instrument Plus at a concentration of 3% for 30 minutes. Then, to dilute the concentrated detergent, use drinking water at a temperature of 30°C. Next, manually clean the instruments with a nylon brush (if clear stains are visible on the surface) and rinse in drinking water. Then wash them in an ultrasonic bath (recommended parameters: frequency 35kHz, power 180 Wef) for 15 minutes in a 1% solution of DENTACLEAN Instrument Plus at 40°C, and rinse, first in drinking water, then in demineralised water. Finally, leave the instruments to dry in a hot-air oven at a temperature of 120°C for 10 minutes.

The surfaces of stainless-steel instruments may corrode if left in saline for longer than is strictly necessary or if saline is allowed to evaporate from the instrument surface. If the instruments come into contact with each other during cleaning or sterilisation, this may cause surface corrosion, as may contact with an already-corroded instrument. Mechanical or chemical erosion on the surface may result in a change in the colour of the anodised titanium. Only a clean and undamaged anodised surface will retain the original colour. The plastic (PEEK) components of some instruments may be damaged by excessive mechanical or thermal stress and also by aggressive chemicals.

Cleaned and disinfected instruments must be stored in a dry place when not in use during surgery (damp could cause them to corrode). Blunt, damaged, or corroded instruments must be discarded and must not be re-used. Corroded instruments must not be sterilised (this risks contaminating the autoclave and other instruments with rust particles and subsequent further corrosion).

## STERILISATION

Stainless steel and titanium instruments are sterilised by moist heat in an autoclave (steam steriliser). Other sterilisation methods must not be used. Hot air sterilisation may distort the structure of metallic and plastic materials and so reduce their lifespan. Plastic cassettes must also not be sterilised with hot air (too high a temperature will damage them). Chemical sterilisation may also interfere with the structure of the materials and must therefore not be used.

### Sterilisation in a cassette

To sterilise surgical instruments in an autoclave, use the plastic cassette that is part of the BioniQ system. Make sure that the sterilisation cassette is correctly positioned in the autoclave. The cassette must not touch the autoclave walls and should be placed centrally.

### Sterilisation in a sterilisation pouch

Another option is to sterilise instruments and components in sterilisation pouches (paper/foil, e.g., Steriking, that meet the requirements of ČSN EN ISO 11607-1 and ČSN EN ISO 11607-2). Place the instruments and components into individual pouches or place the whole cassette into one pouch. Use the appropriate accessories (organisers) to ensure correct steam penetration. The outer PE protective bag must be removed before new instruments and components are sterilised for the first time (sterilise in the primary sterilisation pouch only).

The recommended steam sterilisation method for LASAK stainless steel and titanium instruments and components (validated by LASAK) uses a temperature of 34°C (exposure time 10 minutes). Sterilisation temperatures higher than recommended may damage the instruments. When sterilising instruments in the sterilisation pouch, the appropriate programs with sufficiently long drying cycles must be used (if the instruments are left in a damp sterilisation pouch, this may cause corrosion).

### Precautions

Other moist heat sterilisation methods (except for the recommended options) must not be used (unpackaged components in bulk, in contact with each other, etc.). We recommend sterilising stainless-steel instruments separately from instruments made from different materials. Sterilising titanium tools in a cassette with other (stainless steel) instruments is admissible (where mutual contact is excluded). During sterilisation, the steriliser's maximum permissible load must not be exceeded.

The sterile instruments and components must be kept in the sterilising pouches (protection against microbial contamination), at room temperature, in a dry, dust-free and disinfected place. Pouches containing sterile instruments must be labelled with the sterilisation and expiry dates. When the sterile period has expired, re-sterilisation is necessary. The sterilising cycle must be monitored and documented in accordance with relevant regulations.

The ratchet must always be disassembled for cleaning and disinfection. The ratchet may also be sterilised when assembled (typically in the instrument cassette). The ratchet may only be assembled after all components are completely dry.

Follow the steriliser manufacturer's instructions when sterilising instruments and observe applicable national and international legislation.

In no case does LASAK accept liability for the sterilisation method for the medical devices mentioned when conducted at the end workplace, regardless of which person performed the sterilisation or sterilisation method was used.

IFU-000023 Rev.[01] 2022-09-30

**LASAK s.r.o.** • Českobrodská 1047/46 • 190 01 Prague 9 – Hloubětín • Czech Republic
tel.: +420 224 315 663 • fax: +420 224 319 716 • e-mail: order@lasak.cz • **www.lasak.com**