MANUAL EN

LASAK

Fully guided surgery

Easy and effective

BioniQ®

Introduction

This manual provides dental implantologists, clinicians and related specialists with essential information about the BioniQ fully guided surgical procedure using BioniQ implants inserted at the level of the bone.

The treatment of an edentulous jaw is described as an advanced treatment method in a separate document **Fully guided surgery for an edentulous jaw.**

Disclaimer

Please note that, besides information provided in this manual, knowledge of dental implantology including previous practical experience with, and knowledge of, using the BioniQ implant system is necessary to use BioniQ fully guided surgery.

Preoperative procedures (such as a treatment plan, CT scan, surgical template design and manufacturing, temporary restoration and manufacturing, implant position planning and work with a planning software) as well as postoperative procedures are not part of this paper.

Please read the Terms and Conditions of Use of LASAK guided surgery carefully before you start to use BioniQ fully guided surgery and its related products. The Terms and Conditions of Use of LASAK guided surgery are available on www.lasak.com.

By using BioniQ fully guided surgery and its related products, you agree to be bound by these terms and conditions. If you do not agree with these terms and conditions, do not use BioniQ fully guided surgery and its related products.

Please, note that not all products or services may be available in all countries.

Easy and effective

Contents

GUIDED SURGERY – INTRODUCTION

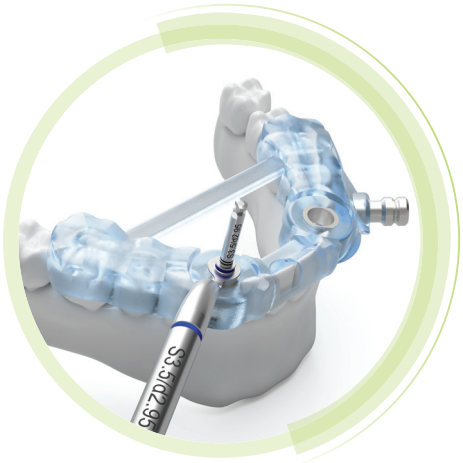
LASAK offers instruments and provides services for pilot and fully guided surgery. This manual provides dental implantologists, clinicians and related specialists with the essential information about the BioniQ fully guided surgical procedure using BioniQ implants inserted at the level of the bone.

Please note that this information only provides a solution for fully guided surgery and does not contain information regarding pilot guided drilling procedures. For more information about BioniQ pilot guided surgery, see the BioniQ pilot guided surgery brochure. BioniQ fully guided surgery is intended for prosthetics driven treatment with BioniQ implants inserted at the level of the bone using a surgical template. A surgical template printed on a 3D printer from certified biocompatible materials guides all instruments in precise trajectories.

The surgical guide is equipped with titanium sleeves with tool stops to achieve the desired osteotomy depth and to ensure the accurate prosthetics position of implant according to the pre-prepared plan.

BENEFITS OF GUIDED SURGERY

- Accurate planning of prosthetic treatment before implantation
- Precise implant position planning concerning anatomical conditions and the best possible use of the bone
- Safe implant insertion into a pre-planned location according to the individual surgical protocol
- The possibility to prepare temporary restoration in advance

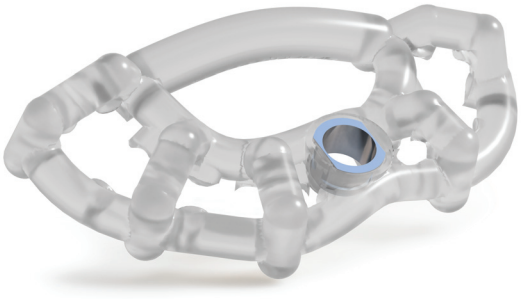


BENEFITS WITH LASAK

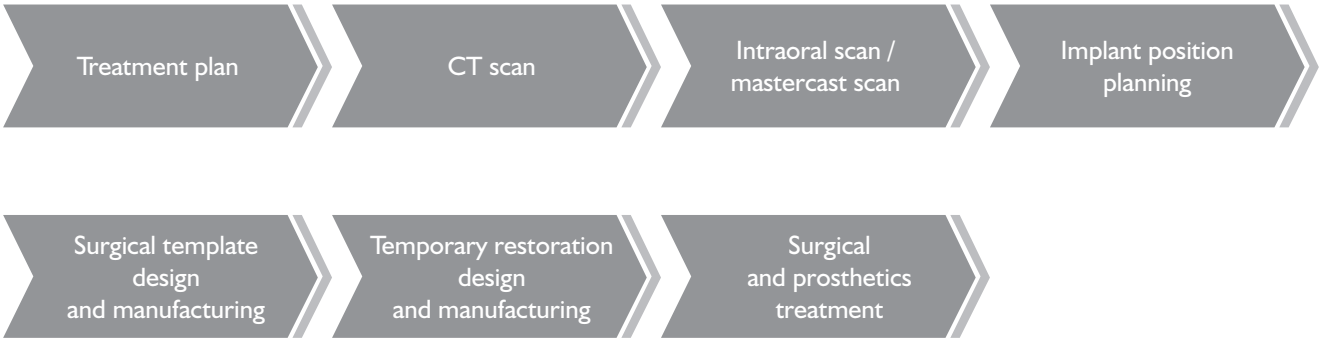
- Quality support and service
- Pilot and fully guided surgery
- Fully guided surgery instruments rental service

SURGICAL TEPLATES

A surgical template is printed based on the CT data and intraoral scan of a patient on a 3D printer from certified biocompatible materials. The surgical template is equipped with titanium sleeves with tool stops for precise tool guidance. It ensures safe implantation into a pre-planned location.



WORKFLOW OF BIONIQ FULLY GUIDED SURGERY



Planning software

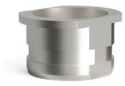
BioniQ fully guided surgery is intended for use with verified three-dimensional planning software. An updated list is available at www.lasak.com. LASAK recommends using Implant Studio® planning software developed by the 3Shape Company.

		Fully guided surgery		Pilot guided surgery	
Company	**Software**	**BioniQ implants**	**BioniQ Plus implants**	**BioniQ implants**	**BioniQ Plus implants**
3Shape	Implant Studio®	✓		✓	
Dental Wings	coDiagnostiX®	✓		✓	✓
Blue Sky Bio	Blue Sky Plan®	✓		✓	
Swissmeda	SMOP	✓	✓	✓	✓
exocad	Exoplan®, DentalCAD	✓	✓	✓	✓
Planmeca	Planmeca Romexis®	✓		✓	✓
Zirkonzahn®	Zirkonzahn Implant-Planner	✓		✓	
ProDigiDent	ImplaStation	✓	✓	✓	✓
Cybermed	OnDemand3D™	✓	✓	✓	✓
ACTEON®	AIS 3D App	✓	✓	✓	✓
3DIEMME®	RealGUIDE® 5.0	✓		✓	

In 5/2022

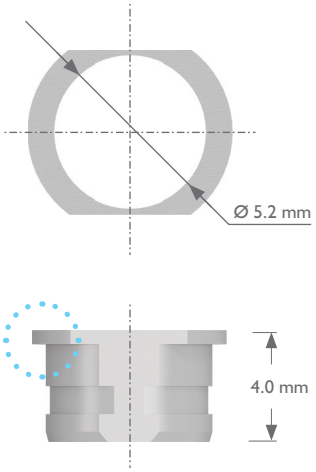
Surgical template and guide sleeves

The surgical template is used to precisely guide instruments during surgery. BioniQ fully guided surgery uses templates that are printed on a 3D printer from certified biocompatible materials. The BioniQ fully guided surgical templates are intended for use only with BioniQ implants inserted at bone level.
The BioniQ fully guided surgery works with a surgical template that is fitted with guide sleeves from the Steco company. The sleeves are a cylindrical shape with an additional rim at the top and an anti-rotation element for precise positioning in the surgical template.



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

Surgical template – inspection windows can help to verify the position of the surgical template.



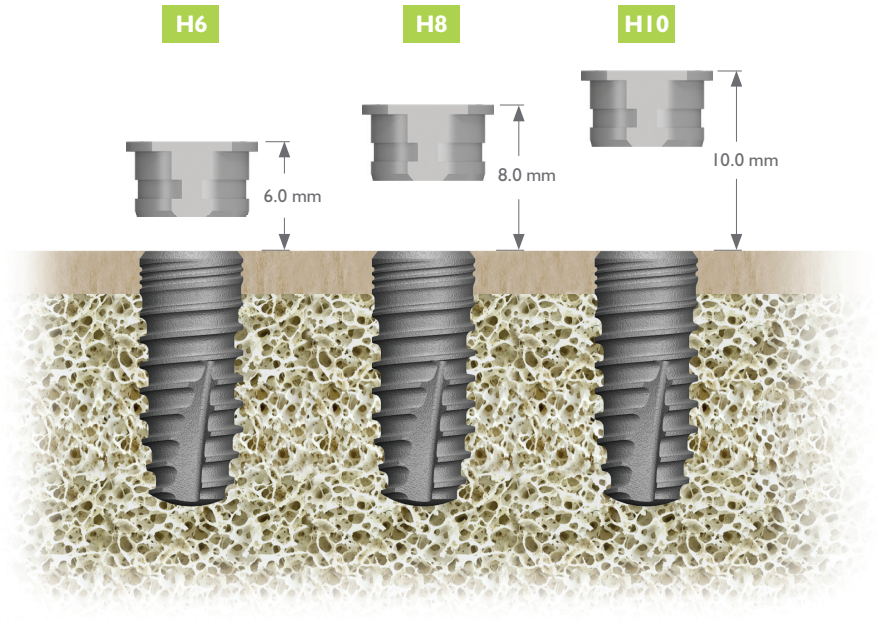
Guide sleeves are equipped with a depth stop

Before using the surgical template

- Confirm that the surgical template corresponds with the preoperative plan.
- Confirm that the positions of the guide sleeves correspond with the preoperative plan.
- Verify that the volume of the surgical template does not prevent manipulation of drill guides and C-guides.
- Verify that the surgical template fits correctly on the patient's teeth.
- Ensure the guide sleeves are firmly anchored in the template.
- Disinfect or sterilize the surgical template according to the manufacturer's instructions.

Guide sleeve positions

BioniQ fully guided surgery has a choice of three distinct height positions of the guided sleeve above the bone (offset). These height positions are denoted H6, H8 and H10 and correspond to the distance of the upper edge of the guide sleeve from the level of the bone in millimeters. The guide sleeve position within the surgical template is determined during the planning phase.

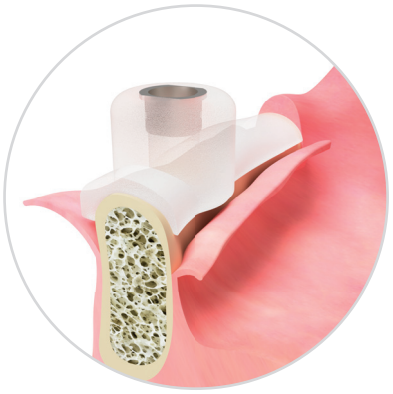


To choose the optimal height position, we advise following these instructions

- Place the guide sleeve as close to the bone or the soft tissue as possible under given anatomical conditions.
- The guide sleeve must not touch the soft tissue under any circumstances.
- Sufficient access for the irrigation instrument must be maintained.

Surgical template placement

Bone supported surgical template fixation involves an initial incision of the mucosa before placing the surgical template. **Mucosa and teeth supported** surgical template fixation do not require the initial incision step before placing the surgical template. Each of these surgical template placement methods has its application. The choice depends on the clinician‘s preference.
The surgical template can be additionally fixed with the fixation pins to increase its stability (page 9).



Bone supported fixation

Teeth supported fixation

Mucosa supported fixation

Drill guides and C-guides

Drill guides and C-guides are auxiliary tools that are used together with the guide sleeve to guide primary tools – drills, countersinks and threadformers. Both of these tools are based on the "sleeve-in-sleeve" concept, which means that the guidance cylinder of the drill guide or the C-guide is inserted into the guide sleeve in the surgical template and additionally sets the required diameter or offset for the specific tool.

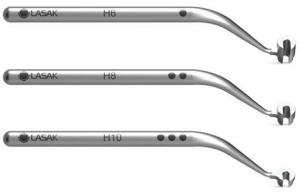
Drill guides

BioniQ fully guided surgery contains four drill guides that differ in the inner diameter of the guidance cylinder. Each drill series has its corresponding drill guide. Drill guides are **color-coded according to the corresponding drill series.**

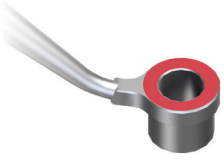
Instrument	Color-code	Ref. No.	Guidance cylinder inner diameter
Drill guide S2.9 (GS)	■	2513.00	Ø 2.35 mm
Drill guide S3.5 (GS)	■	2514.00	Ø 3.00 mm
Drill guide S4.0/T4.0 (GS)	■ ■	2515.00	Ø 3.40 mm
Drill guide S5.0/T5.0 (GS)	■ ■	2516.00	Ø 4.30 mm

C-guides

BioniQ fully guided surgery contains three C-guides that differ in the height of the guidance cylinder. Each of them corresponds to a particular height position (offset) of the guide sleeve (H6, H8 and H10). The different height of the guidance cylinder compensates offset of the guide sleeve from the bone level. C-guides are **marked with a symbol that makes it easier to identify the tool.**

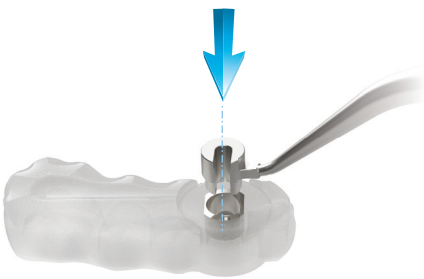


Instrument	Symbol-code	Ref. No.	Guide sleeve position (offset)
C-guide H6 (GS)	●	2520.00	H6
C-guide H8 (GS)	● ●	2518.00	H8
C-guide H10 (GS)	● ● ●	2517.00	H10



Drill guides have a fully circular shape and are only used for drilling.

C-guides have the shape of a letter "C" and are used to guide countersinks and threadformers.



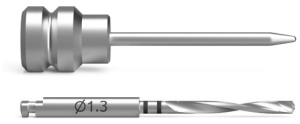
Sleeve-in-sleeve concept

Surgical template fixation

The stability of the surgical template is crucial to the accuracy of the surgical procedure. BioniQ fully guided surgery has two options for surgical template fixation – by horizontal and vertical fixation pins. The fixation of the surgical template is especially useful for edentulous patients. The treatment of an edentulous jaw is described as an advanced treatment method in a separate document **Fully guided surgery for an edentulous jaw**.

Guided fixation pins – horizontal

The horizontal fixation pins are used to anchor the surgical template **during the initial phase of the surgical procedure**. These pins are placed in a pre-drilled hole in the cortical bone and guided by a fixation guide sleeve in the surgical template. The pre-drilled hole is formed by a guided drill for pin, d1.3 (GS). The horizontal fixation pins are guided transmucosally and are held in place by surface friction. They can be easily removed during the surgery procedure.

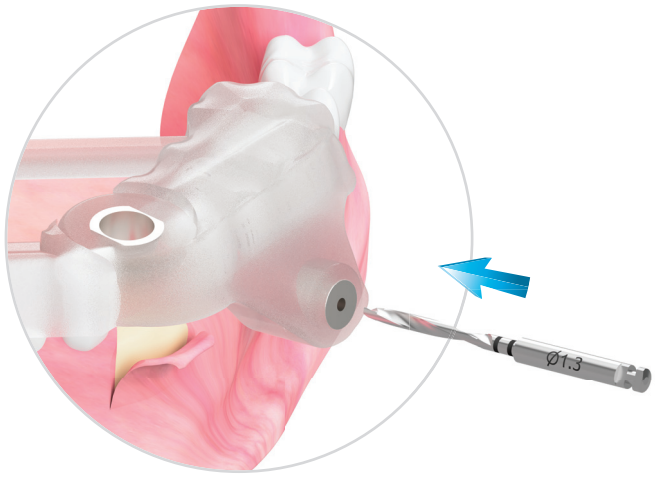


Instrument	Ref. No.	Diameter	Effective length
Guided fixation pin – horizontal, d1.3/L25/L17 (GS)	2526.00	Ø 1.3 mm	17.0 mm
Guided drill for pin, d1.3 (GS)	2527.00	Ø 1.3 mm	18.5 mm

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

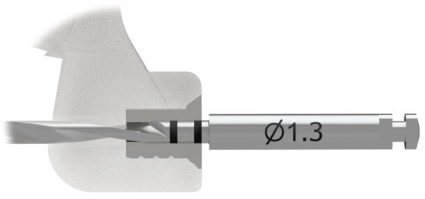
Caution

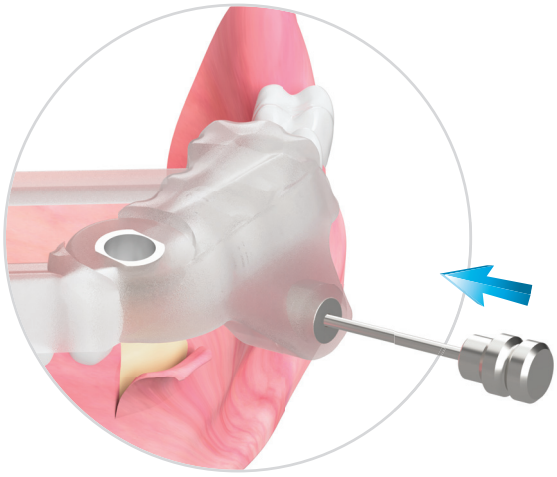
- Select the number of horizontal fixation pins carefully, this affects the accuracy and stability of the surgical template, and also its manipulability during the surgical procedure and the subsequent impact on the patient.
- Inclination and depth of the horizontal fixation pins are important, easy access should be ensured.
- The horizontal fixation pins must be placed in a sufficient volume of cortical bone.
- Mouth opening capability should be taken into consideration.



Insert the guided drill for pin into the appropriate fixation guide sleeve. Drill up to about half the length of the drill, then remove the bone fragments by retracting the drill back. Continue drilling to the second laser mark from the tip of the drill.

Maximum drilling speed is 800 rpm.





Insert the guided fixation pin – horizontal into the prepared hole.

The horizontal fixation pin passing through the fixation guide sleeve anchoring the surgical template in the cortical bone.

The horizontal fixation pin should be placed to the pin stop.

Guided fixation pins – vertical

The vertical fixation pins are used to ensure the additional stabilization of the surgical template after the implant placement phase. These pins are placed into the inserted implant and guided by the guide sleeve. The vertical fixation pins provide the surgical template fixation in all directions. The vertical fixation pins are color-coded in accordance with the color of the prosthetic platform. Yellow for the QN prosthetic platform (implants S2.9), blue for the QR prosthetic platform (implants S3.5, S4.0/T4.0 and S5.0/T5.0).

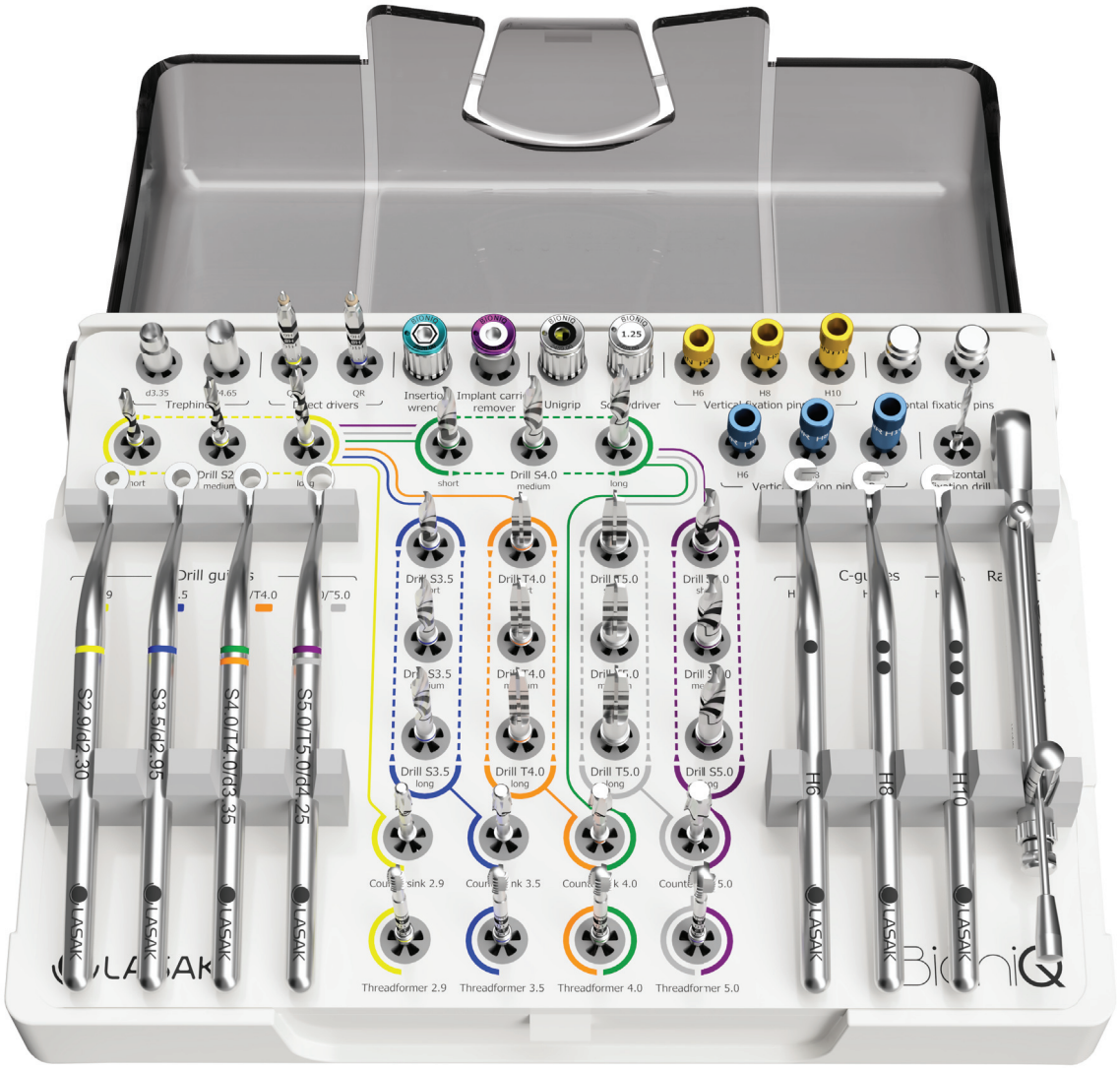
Instrument	Platform	Ref. No.	Diameter	Height
Guided fixation pin – vertical, QN/H6/d5.2 (GS)	●	2523.06	Ø 5.2 mm	15.4 mm
Guided fixation pin – vertical, QN/H8/d5.2 (GS)	●	2523.08	Ø 5.2 mm	17.4 mm
Guided fixation pin – vertical, QN/H10/d5.2 (GS)	●	2523.10	Ø 5.2 mm	19.4 mm
Guided fixation pin – vertical, QR/H6/d5.2 (GS)	●	2525.06	Ø 5.2 mm	15.8 mm
Guided fixation pin – vertical, QR/H8/d5.2 (GS)	●	2525.08	Ø 5.2 mm	17.8 mm
Guided fixation pin – vertical, QR/H10/d5.2 (GS)	●	2525.10	Ø 5.2 mm	19.8 mm

Vertical fixation pin passing through the guide sleeve anchoring the surgical template in the BioniQ implant.

When choosing the vertical fixation pin, check the guide sleeve position (H6, H8 or H10) and the type of the implant platform (QN – yellow or QR – blue).

Instruments for BioniQ fully guided surgery

- Instruments for Straight and Tapered implants in one cassette
- Intuitive easy-to-follow instrument organizer
- Compact dimensions



The instruments included in the organizer of surgical instruments are sufficient for bone bed preparation for all implant series. **The lifetime for the use of trephines, guided drills, countersinks and threadformers is limited to 20 applications**. To a large extent, the wear on the drills depends on the density of the bone being prepared. **Worn tools must be replaced with new ones**.

The instrument's quality and service life depends on adherence to the recommended maintenance and care procedures. Disinfection and cleaning must be done immediately following the instrument's use. For more information, see the chapter Cleaning and Sterilization on page 31.

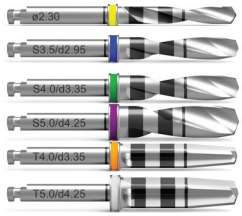
Trephines

Trephine for guided surgery, d3.35 (GS)	2521.00
Trephine for guided surgery, d4.65 (GS)	2522.00

Drill for fixation pin

Guided drill for pin, d1.3 (GS)	2527.00

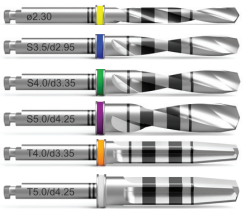
Guided drills – short



Guided drill S2.9 – short (GS)	2484.00
Guided drill S3.5 – short (GS)	2487.00
Guided drill S4.0 – short (GS)	2490.00
Guided drill S5.0 – short (GS)	2493.00
Guided drill T4.0 – short (GS)	2497.00
Guided drill T5.0 – short (GS)	2500.00

Overall length of the short drill is 31.5 mm.

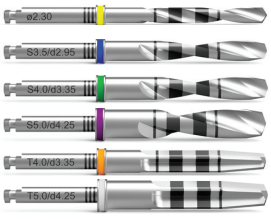
Guided drills – medium



Guided drill S2.9 – medium (GS)	2486.00
Guided drill S3.5 – medium (GS)	2488.00
Guided drill S4.0 – medium (GS)	2491.00
Guided drill S5.0 – medium (GS)	2494.00
Guided drill T4.0 – medium (GS)	2498.00
Guided drill T5.0 – medium (GS)	2501.00

Overall length of the medium drill is 35.5 mm.

Guided drills – long



Guided drill S2.9 – long (GS)	2485.00
Guided drill S3.5 – long (GS)	2489.00
Guided drill S4.0 – long (GS)	2492.00
Guided drill S5.0 – long (GS)	2495.00
Guided drill T4.0 – long (GS)	2499.00
Guided drill T5.0 – long (GS)	2502.00

Overall length of the long drill is 39.5 mm.

Countersinks for guided surgery

Countersink S2.9 for guided surgery (GS)	2504.00
Countersink S3.5 for guided surgery (GS)	2506.00
Countersink S4.0/T4.0 for guided surgery (GS)	2508.00
Countersink S5.0/T5.0 for guided surgery (GS)	2510.00

Instruments

Threadformers for guided surgery

Threadformer S2.9 for guided surgery (GS)	2503.00
Threadformer S3.5 for guided surgery (GS)	2505.00
Threadformer S4.0/T4.0 for guided surgery (GS)	2507.00
Threadformer S5.0/T5.0 for guided surgery (GS)	2509.00

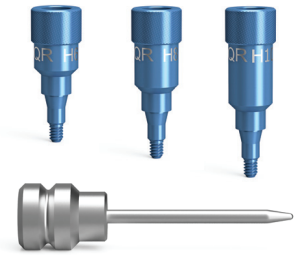
Drill guides

Drill guide for guided drill S2.9 (GS)	2513.00
Drill guide for guided drill S3.5 (GS)	2514.00
Drill guide for guided drill S4.0/T4.0 (GS)	2515.00
Drill guide for guided drill S5.0/T5.0 (GS)	2516.00

C-guides

C-guide for guided surgery, H6 (GS)	2520.00
C-guide for guided surgery, H8 (GS)	2518.00
C-guide for guided surgery, H10 (GS)	2517.00

Fixation pins



Guided fixation pin – vertical, QR/H6/d5.2 (GS)	●	2525.06
Guided fixation pin – vertical, QR/H8/d5.2 (GS)	●	2525.08
Guided fixation pin – vertical, QR/H10/d5.2 (GS)	●	2525.10
Guided fixation pin – vertical, QN/H6/d5.2 (GS)	●	2523.06
Guided fixation pin – vertical, QN/H8/d5.2 (GS)	●	2523.08
Guided fixation pin – vertical, QN/H10/d5.2 (GS)	●	2523.10
Guided fixation pin – horizontal, d1.3/L25/L17 (GS)		2526.00

Overall length of the horizontal guided fixation pin is 25 mm.

Insertion wrenches

Insertion wrench BioniQ – hex 2.5/L17.5 (GS)	2528.00
Direct Driver QR – mechanical, QR/ISO/L18 (GS)	2531.00
Direct Driver QN – mechanical, QN/ISO/L18 (GS)	2530.00

Insertion wrench BioniQ (Ref. No. 2528.00) is primary implant insertion instrument.
The Direct Driver is used for implant insertion after removal of the implant carrier and for the final correction of the position of an already inserted implant (alignment of the internal hex or correction of the implant height).

Implant carrier remover

Implant carrier remover (GS)	2529.00

Sleeves for guided surgery

Steco sleeve – with depth stop for fully guided surgery, d5.20 (GS)	M.27.15.D520
Steco sleeve – with depth stop for drill for pin, d1.3 (GS)	M.27.24.D130L5

SURGICAL PROCEDURE

As an example of a surgical procedure, situations for the insertion of a BioniQ implant S3.5/L10 are shown. In these examples, a teeth supported surgical template and flap surgical procedure is considered. The treatment of an edentulous jaw is described as an advanced treatment method in a separate document **Fully guided surgery for an edentulous jaw**.

1) Incising gingiva (optional step)

For the flap surgical procedure, uncover the bone by an incision. The incision direction and execution depend on the case.
For the flapless surgical technique, use the trephine for guided surgery as shown on page 16.

2) Surgical template placement

Place the surgical template according to the type of mounting (bone, mucosa or teeth supported fixation). Verify the fit and stability of the surgical template.
For more information on the surgical templates, see chapters Surgical Template and Guide Sleeves (page 6) and Surgical Template Placement (page 7).

3) Surgical template fixation – horizontal (optional step)

The stability of the surgical template is crucial for the accuracy of the surgical procedure. Use the fixation pins for maximum stability of the surgical template.
For more information on the surgical template fixation, see the chapter Surgical Template Fixation on page 9.

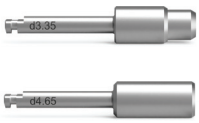
4) Opening gingiva (optional step)

Optional step in case of flapless surgery procedure using mucosa or teeth supported fixation of the surgical template.

There are two trephines available. The trephine for guided surgery – d3.35 (GS) is designed for the S2.9 and S3.5 implants. The trephine for guided surgery – d4.65 (GS) is designed for the S4.0/T4.0 and S5.0/T5.0 implants.

Choose the trephine for guided surgery d3.35 or d4.65 depending on the implant series (implant diameter).
Insert the trephine into the guide sleeve and gently cut a circular piece of the soft tissue with the trephine.
Clean the area.

Maximum cutting speed is 15 rpm.

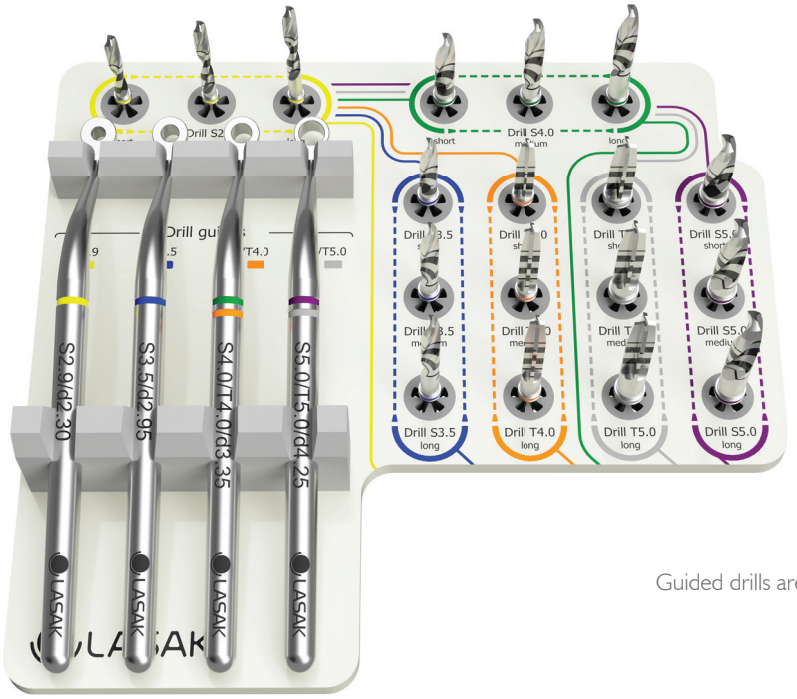


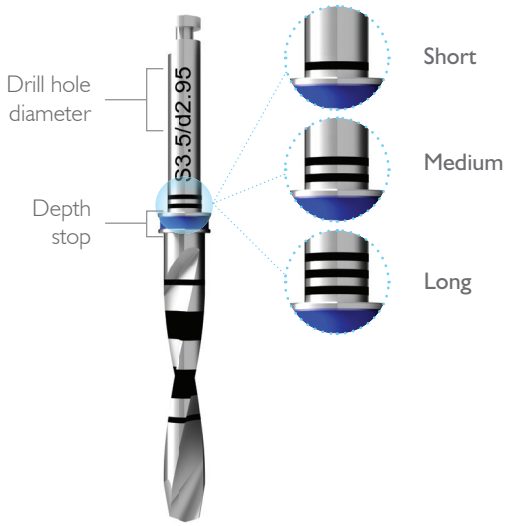
Instrument	Ref. No.	Outer diameter	Corresponding implant series
Trephine for guided surgery, d3.35 (GS)	2521.00	Ø 4.2 mm	S2.9 S3.5
Trephine for guided surgery, d4.65 (GS)	2522.00	Ø 5.15 mm	S4.0/T4.0 S5.0/T5.0

No auxiliary guide tool is used in this step.

5) Implant bed basic preparation – drilling

The implant bed is first prepared by the guided drills using the corresponding drill guide. **The color of the drill guide must match the color of the guided drill**. Always use a drill and a guide wrench of the same color for drilling. The procedure for using guided drills is clearly described on page 18 and it is also printed on the BioniQ fully guided surgery cassette.





Guided drills are color-coded according to the corresponding drill series. Laser marks indicate the length of the guided drill.

Each drill series has its corresponding drill guide. Drill guides are color-coded according to the corresponding drill series.

Caution

- The maximum drilling speed is 800 rpm.
- During preparation, use sufficient external cooling of drills with cold sterile saline (5 °C, 41 F).
- The guided drill must not rotate during its insertion into the drill guide.
- The guided drill has to move freely through the drill guide.
- Avoid lateral pressure on the guided drill.
- Drill intermittently.

Auxiliary guide tool is used in this step.

Surgical procedure

Drilling sequence

The drilling sequence depends on the implant series. Regardless of the implant diameter and implant type (straight or tapered), start with the yellow Guided drill S2.9 (GS). During the surgery, follow the illustrations printed on the BioniQ fully guided surgery cassette. Three drill lengths (short, medium and long) are available per guided drill type. **The colored oval means: "choose one guided drill out of the three".**

Choose one of the drills:

Short

Overall length of the short drills is 31.5 mm

Medium

Overall length of the medium drills is 35.5 mm

Long

Overall length of the long drills is 39.5 mm

S2.9

Guided drill S2.9
short/medium/long

S3.5

Guided drill S2.9
short/medium/long

Guided drill S3.5
short/medium/long

T4.0

Guided drill S2.9
short/medium/long

Guided drill T4.0
short/medium/long

S4.0

Guided drill S2.9
short/medium/long

Guided drill S4.0
short/medium/long

T5.0

Guided drill S2.9
short/medium/long

Guided drill S4.0
short/medium/long

Guided drill T5.0
short/medium/long

S5.0

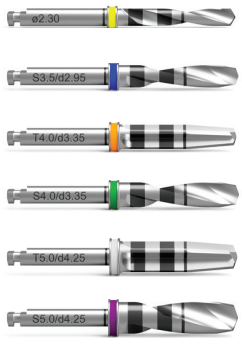
Guided drill S2.9
short/medium/long

Guided drill S4.0
short/medium/long

Guided drill S5.0
short/medium/long

Drilling instructions

Consult the surgical protocol to determine the type of the implant series, the implant length and the guide sleeve position (offset). Depending on the implant series, select the required guided drills. Guided drills are color-coded. The color on the final drill corresponds to the color of the implant line (implant diameter).
Adhering to the recommended drilling procedure is obligatory and minimizes the risks of excessive mechanical or thermal damage to the bone tissue.



Instrument	Length	rpm	S2.9	S3.5	T4.0	S4.0	T5.0	S5.0
Guided drill S2.9 (GS)	short/medium/long	800						
Guided drill S3.5 (GS)	short/medium/long	800						
Guided drill T4.0 (GS)	short/medium/long	800						
Guided drill S4.0 (GS)	short/medium/long	800						
Guided drill T5.0 (GS)	short/medium/long	800						
Guided drill S5.0 (GS)	short/medium/long	800						

Guided drill length options

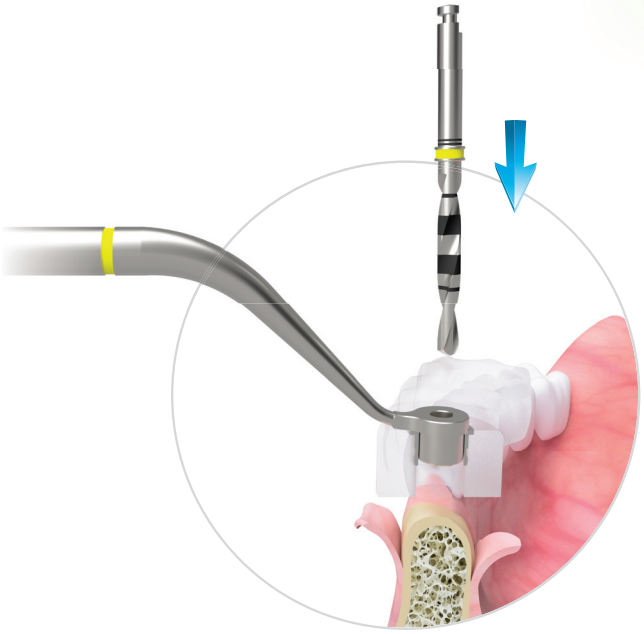
Depending on the implant length and the guide sleeve position/offset (H6, H8 or H10), select lengths of these guided drills. Three drill lengths (short, medium and long) are available per guided drill type. The drill length is indicated by one (short), two (medium) or three (long) laser marks on the drill shank. **The choice of a guided drill length depends on the desired implant length and distance of the guide sleeve from the bone level according to the below table**. Information on the drill length required for preparation in every single location can also be found in the surgical protocol.

Implant length	Distance of sleeve from the bone level (offset)		
	H6	H8	H10
L8	Short drill		Medium drill
L10		Medium drill	
L12	Medium drill		Long drill
L14		Long drill	
L16	Long drill		

The guided drill must always be used together with the corresponding drill guide. **The color of the drill guide must match the color of the guided drill**. Final guided drills and Drill guides are color-coded according to the corresponding implant series (implant diameter). For more information on the drill guides, see chapter Drill Guides and C-guides (page 8).

Instrument	Color-code	Ref. No.	Guidance cylinder inner diameter
Drill guide S2.9 (GS)		2513.00	Ø 2.35 mm
Drill guide S3.5 (GS)		2514.00	Ø 3.00 mm
Drill guide S4.0/T4.0 (GS)		2515.00	Ø 3.40 mm
Drill guide S5.0/T5.0 (GS)		2516.00	Ø 4.30 mm

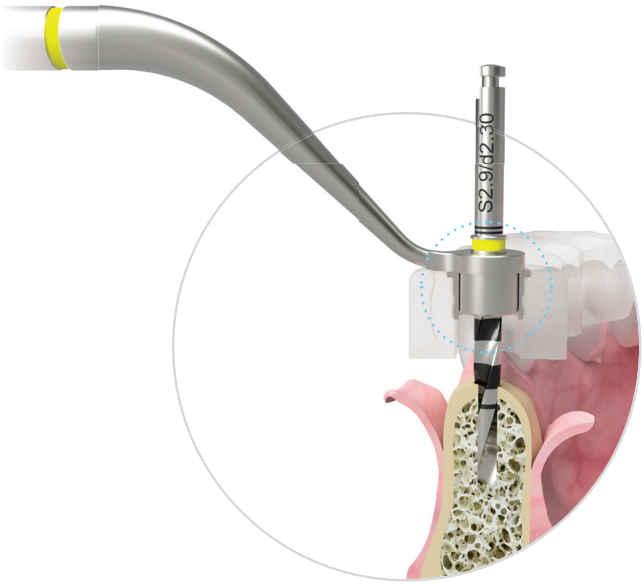
Surgical procedure

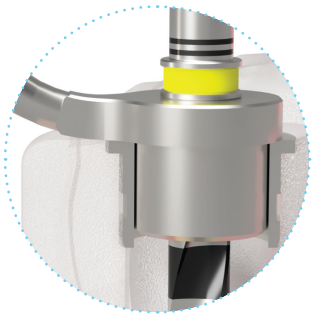


Pilot drill

Regardless of the implant diameter and implant type (straight or tapered), start with the guided drill S2.9 (GS) using a drill guide of the same color.
Insert the cylindrical part of the drill guide into the guide sleeve in the surgical template. Insert the guided drill into the drill guide and start drilling. **The color of the drill guide must match the color of the guided drill.**

The guided drill must not rotate during its insertion into the drill guide.





Drill until the collar of the guided drill hits the cylinder of the drill guide in order to achieve the desired osteotomy depth.

Maximum drilling speed is 800 rpm.
Drill intermittently.

Final drill

If the surgical protocol specifies more than one guided drill per implant site, continue with the next guided drill and the corresponding drill guide until the required diameter of the osteotomy is reached.

Maximum drilling speed is 800 rpm.
Drill intermittently.

6) Implant bed subsequent preparation

The subsequent implant bed preparation involves the use of countersinks and threadformers. The countersinks and threadformers are used together with C-guides. C-guides have the shape of a letter "C" and are used to guide countersinks and threadformers to achieve the required milling/thread depth.
The procedure is clearly printed on the BioniQ fully guided surgery cassette and is described in table below.
The countersinks and the threadformers are laser-marked and color-coded so that they can be clearly matched to the corresponding implant series.

Threadformers for guided surgery cannot be used for preparation without the use of a surgical template due to differences in laser depth marks.

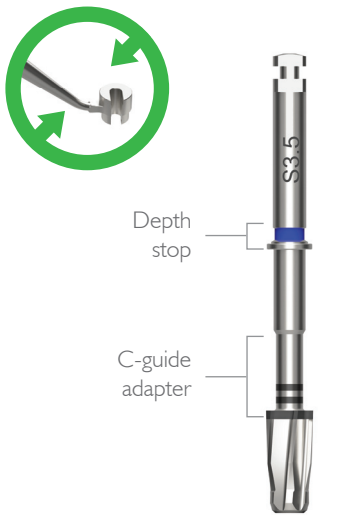
The countersink is used for all bone types (from D1 to D4). In D4 density bone, it is possible to perforate a thin section of cortical bone with partial use of the countersink.
The threadformer is used in D1 and D2 density bones to the total length of the implant. It is not necessary to use the threadformer in lower density bones (D3 and D4).

	Instrument	rpm	S2.9	S3.5	T4.0	S4.0	T5.0	S5.0
	Countersink S2.9 for guided surgery (GS)	500	■					
	Threadformer S2.9 for guided surgery (GS)	20	☒					
	Countersink S3.5 for guided surgery (GS)	500		■				
	Threadformer S3.5 for guided surgery (GS)	20		☒				
	Countersink S4.0/T4.0 for guided surgery (GS)	500			■	■		
	Threadformer S4.0/T4.0 for guided surgery (GS)	20			☒	☒		
	Countersink S5.0/T5.0 for guided surgery (GS)	400					■	■
	Threadformer S5.0/T5.0 for guided surgery (GS)	20					☒	☒

■ obligatory use ☒ optional use

Subsequent preparation – using a countersink

BioniQ fully guided surgery has a total of four countersinks and three C-guides (H6, H8 and H10) that are used for milling.
If the implant insertion requires a torque that is too high, this may be due to not using a countersink. The countersink must be used because of the shape of the implant, which is not completely cylindrical, even for the straight implants. Part of the neck section of the implant is conical, while the implant bed prepared using only a drill is not, until a countersink is used. The proper use of the countersink ensures optimum stress distribution in the area of marginal bone and prevents an excessive mechanical load on the bone in the area of the implant neck.



Countersinks are color-coded according to the corresponding implant series.

Caution

- The maximum milling speed is 500 rpm, for the countersink S5.0/T5.0, 400 rpm.
- During preparation, use sufficient external cooling of the countersinks with cold sterile saline (5 °C, 41 F).
- The countersink must not rotate during its insertion into the surgical template.
- The countersink has to move freely through the C-guide.

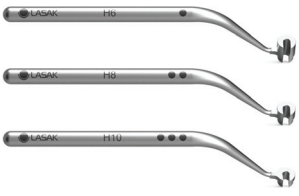
Instructions

Consult the surgical protocol to determine the type of the implant series and the guide sleeve position (offset). Depending on the implant series (implant diameter), select the required countersink for guided surgery. Countersinks for guided surgery are color-coded according to the corresponding implant series (implant diameter).
Adhering to the recommended milling procedure is obligatory and minimizes the risks of excessive mechanical or thermal damage to the bone tissue.

Instrument	rpm	S2.9	S3.5	T4.0	S4.0	T5.0	S5.0
Countersink S2.9 for guided surgery (GS)	500	■					
Countersink S3.5 for guided surgery (GS)	500		■				
Countersink S4.0/T4.0 for guided surgery (GS)	500			■	■		
Countersink S5.0/T5.0 for guided surgery (GS)	400					■	■

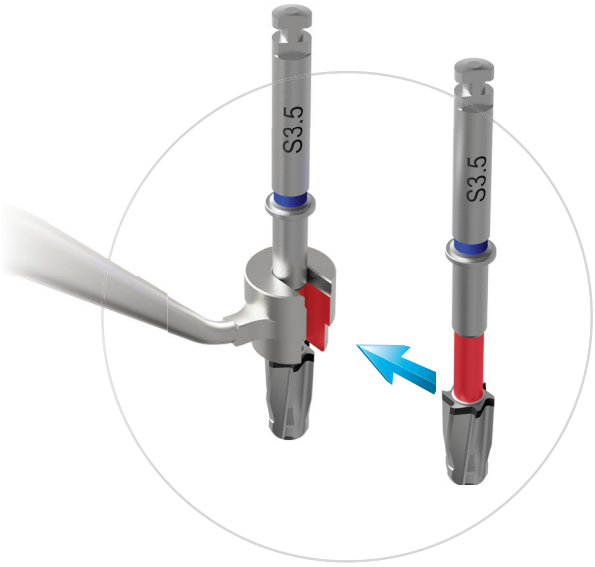
■ obligatory use

Depending on the particular guide sleeve position/offset (H6, H8 or H10), select the corresponding C-guide marked with the same name (H6, H8 or H10). Information on the C-guide required for preparation in every single location can also be found in the surgical protocol. For more information on the C-guides, see chapter Drill Guides and C-guides (page 8).



Instrument	Symbol-code	Ref. No.	Guide sleeve position (offset)
C-guide H6 (GS)	●	2520.00	H6
C-guide H8 (GS)	●●	2518.00	H8
C-guide H10 (GS)	●●●	2517.00	H10

Auxiliary guide tool is used in this step.



Insert the cylindrical narrow part of the countersink ("C-guide adapter") into the C-guide. Slide the countersink into the groove laterally.

Insert the assembly of countersink and C-guide into the surgical template. The countersink must not rotate during its insertion into the surgical template.

Starting position to initiate milling. The assembly of the countersink and C-guide is inserted into the surgical template. The C-guide is correctly placed in the guide sleeve and the countersink moves freely through the C-guide.

After inserting the assembly of the countersink and C-guide into the surgical template, start milling.

Mill until the collar of the countersink hits the cylinder of the C-guide to achieve the desired osteotomy depth.

Maximum milling speed is 500 rpm; for countersink S5.0/T5.0 400 rpm.

Subsequent preparation – using a threadformer

The threadformer is used in D1 and D2 density bones to the total length of the implant. It is not necessary to use the threadformer in lower density bones (D3 and D4), or it can be used to cut the cortical bone.
Proper use of the threadformer provides a favorable stress distribution in the bone during implant placement. The use of the threadformer can help to reduce the implant insertion torque.

Caution

- The maximum threading speed is 20 rpm.
- During preparation, use sufficient external cooling of threadformer with cold sterile saline (5 °C, 41 F).
- The threadformer must not rotate during its insertion into the surgical template.
- The threadformer has to move freely through the C-guide.

Threadformers are not equipped with a depth stop.
Threadformers for guided surgery cannot be used for preparation without the use of a surgical template due to differences in laser depth marks.

Threadformers are color-coded according to the corresponding implant series.

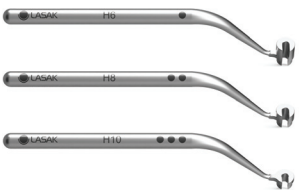
Instructions

Consult the surgical protocol to determine the type of the implant series (implant diameter) and the guide sleeve position (offset). Depending on the implant series (implant diameter), select the required threadformer for guided surgery. Threadformers for guided surgery are color-coded according to the corresponding implant series.
Adhering to the recommended threading procedure is obligatory and minimizes the risks of excessive mechanical or thermal damage to the bone tissue.

Instrument	rpm	S2.9	S3.5	T4.0	S4.0	T5.0	S5.0
Threadformer S2.9 for guided surgery (GS)	20						
Threadformer S3.5 for guided surgery (GS)	20						
Threadformer S4.0/T4.0 for guided surgery (GS)	20						
Threadformer S5.0/T5.0 for guided surgery (GS)	20						

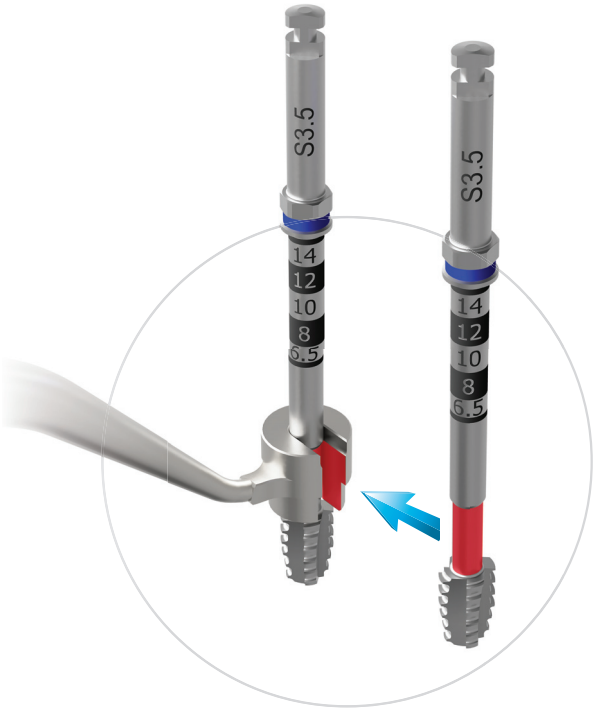
optional use

Depending on the particular guide sleeve position/offset (H6, H8 or H10), select the corresponding C-guide marked with the same name (H6, H8 or H10). Information on the C-guide required for preparation in every single location can also be found in the surgical protocol. For more information on the C-guides, see the chapter Drill guides and C-guides (page 8).



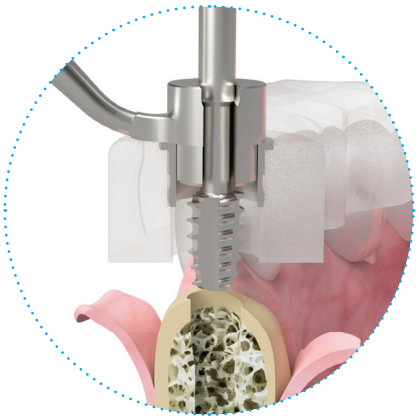
Instrument	Symbol-code	Ref. No.	Guide sleeve position (offset)
C-guide H6 (GS)	●	2520.00	H6
C-guide H8 (GS)	●●	2518.00	H8
C-guide H10 (GS)	●●●	2517.00	H10

Auxiliary guide tool is used in this step.

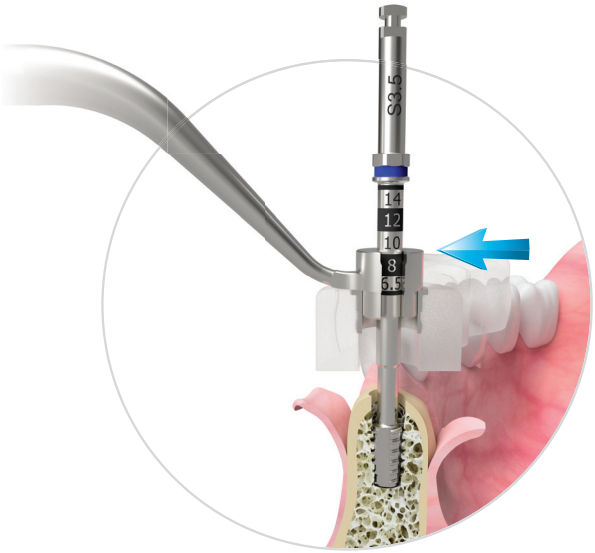


Insert the cylindrical narrow part of the threadformer (“C-guide adapter”) into the C-guide. Slide the threadformer into the groove laterally.

Insert the assembly of threadformer and C-guide into the surgical template. The threadformer must not rotate during its insertion into the surgical template.



The starting position to initiate threading. The assembly of the threadformer and C-guide is inserted into the surgical template. The C-guide is correctly placed in the guide sleeve and the threadformer moves freely through the C-guide.



After inserting the assembly of threadformer and C-guide into the surgical template, start threading.

Threadformers are not equipped with a depth stop!
Use the conventional depth marks to achieve the required thread depth.

Threadformers for guided surgery cannot be used for preparation without the use of a surgical template due to differences in laser depth marks..

Maximum threading speed is 20 rpm.

7) Implant placement

Implant placement – using an insertion wrench

Implants may be inserted manually using the insertion wrench BioniQ (GS) for guided surgery and the ratchet, or mechanically using the Direct Driver – mechanical (GS) and a surgical unit. Insertion wrench BioniQ (GS) is primary implant insertion instrument. The Direct Driver (GS) is used for the implant insertion after removal of the implant carrier and for the final correction of the position of an already inserted implant (alignment of the internal hex or correction of the implant depth).

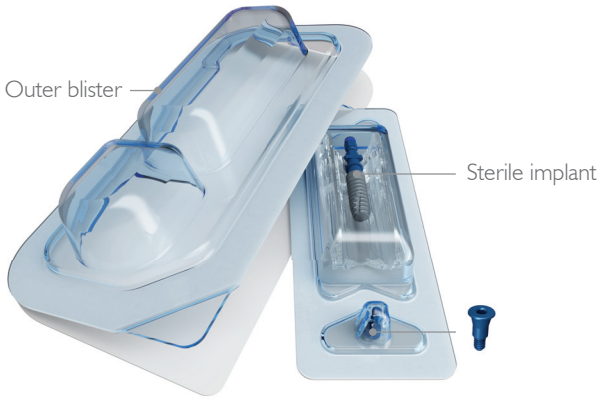
Insertion wrench BioniQ (GS)

The depth control is managed by the depth marks that correspond to the respective guide sleeves offsets, H6, H8 and H10.

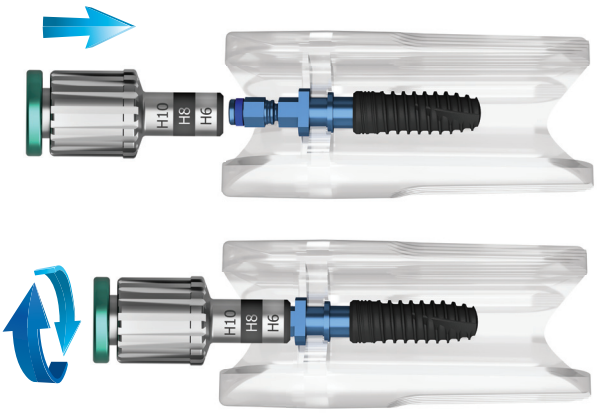
The depth marks correspond to the bone-level implant only.
The depth marks do not allow the insertion of BioniQ Plus implants.

Instructions

Consult the surgical protocol to determine the guide sleeve position/offset (H6, H8 or H10).
Open the implant package. The BioniQ implant package contains a sterile cover screw. To remove the implant from the inner blister, peel off the paper from the back of the inner blister to about three quarters of its length to prevent the cover screw falling out of the package. Attach the insertion wrench BioniQ (GS) to the implant carrier and use it to pull out the implant from the plastic holder using a twisting motion. The implant is now ready for insertion.

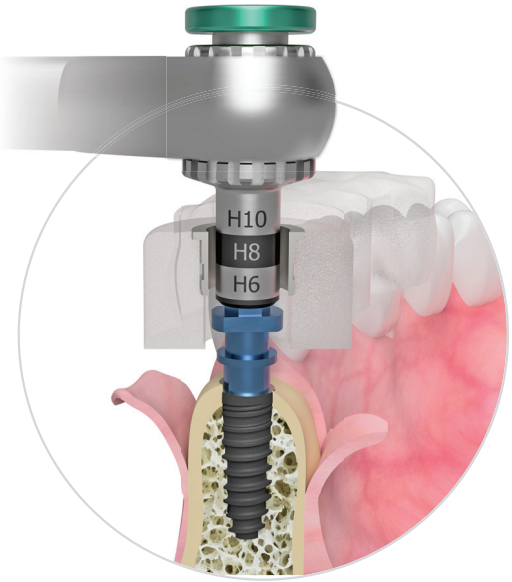


The BioniQ implant package contains a sterile cover screw.



No auxiliary guide tool is used in this step.

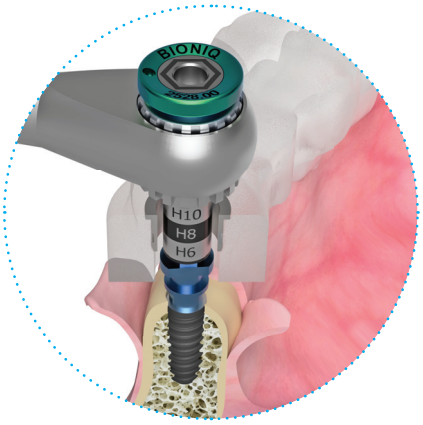
Using the insertion wrench BioniQ (GS), place the implant with the implant carrier into the respective guide sleeve of the surgical template.
Insert the implant into the bone by turning the insertion wrench (GS) clockwise.
Align the axis of the assembly to the axis of the guide sleeve.



Use the ratchet to load the implant into the prepared bone bed. The ratchet has to be held only at the end of the spring indicator wire.

The maximum recommended insertion torque of BioniQ implants is 60 Ncm.

Exceeding the torque of 60 Ncm may result in damage to the torque adapter of the instruments or the implant's internal geometry, or may cause sticking of the implant carrier in the implant.

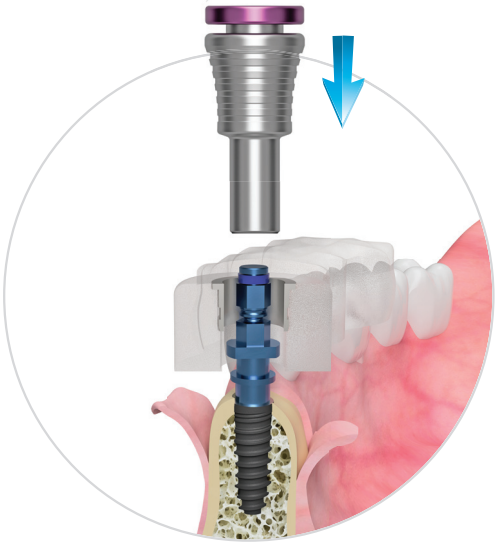


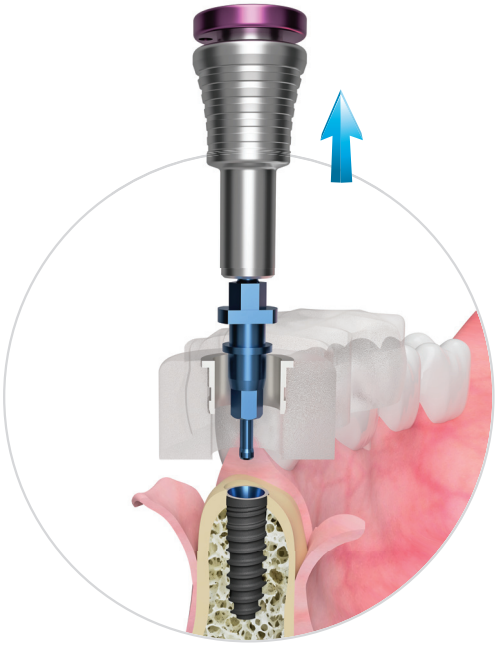
The laser marked hexagon on the insertion wrench matches the orientation of the inner hexagon of the implant.

Insertion wrench BioniQ (GS) is not equipped with a depth stop! Use the conventional depth marks to achieve the required thread depth.

Pull the insertion wrench (GS) out of the implant carrier.

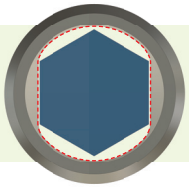
Surgical procedure



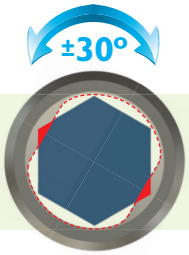


Use the implant carrier remover for easier removal of the implant carrier from the inserted implant.

Schematic representation of the implant carrier remover principle. View inside from bottom..

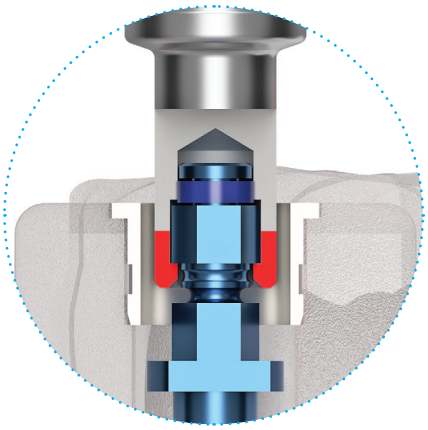


The surfaces of the upper hexagon of the implant carrier are parallel to the flat surfaces inside the implant carrier remover.



Turning the implant carrier remover +- 30° catch the implant carrier on the lower edge of the upper hexagon.

Slightly (+- 30°) turn clock- / counterclockwise the carrier remover. Two pads inside the implant carrier remover catch the implant carrier on the lower edge of the upper hexagon.



Pull the implant carrier out of the implant.

Implant placement – using a Direct Driver

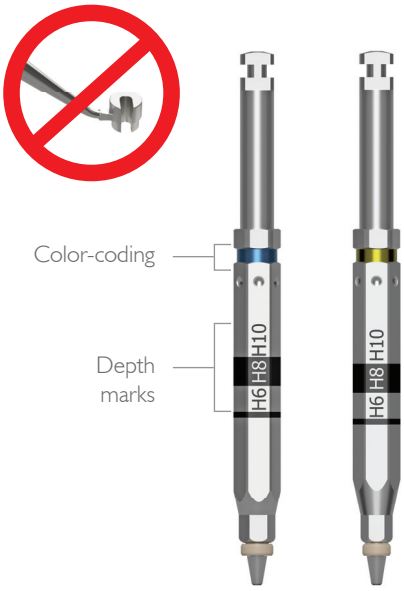
Implants may be inserted manually using the insertion wrench BioniQ (GS) for guided surgery and the ratchet, or mechanically using the Direct Driver – mechanical (GS) and a surgical unit. Insertion wrench BioniQ (GS) is primary implant insertion instrument. The Direct Driver is used for the implant insertion after removal of the implant carrier and for final correction of the position of an already inserted implant (alignment of the internal hex or correction of the implant depth).

Do not exceed the speed of 20 rpm.

The depth control is managed by the depth marks that correspond to the respective guide sleeves offsets, H6, H8 and H10.

The depth marks correspond to the bone-level implant only. The depth marks do not allow the insertion of BioniQ Plus implants.

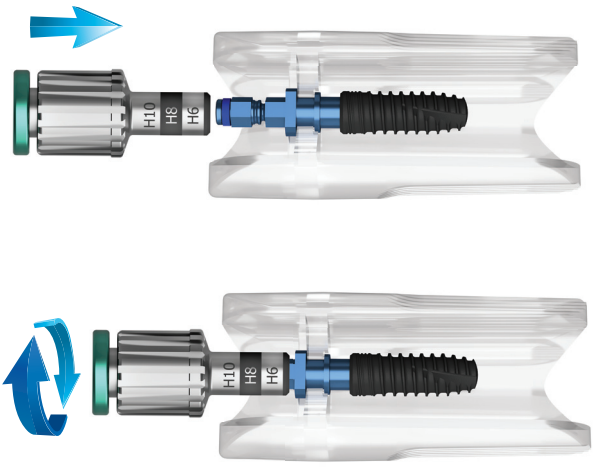
Thre Direct Driver (GS) cannot be used without the use of a surgical template due to differences in laser depth marks.

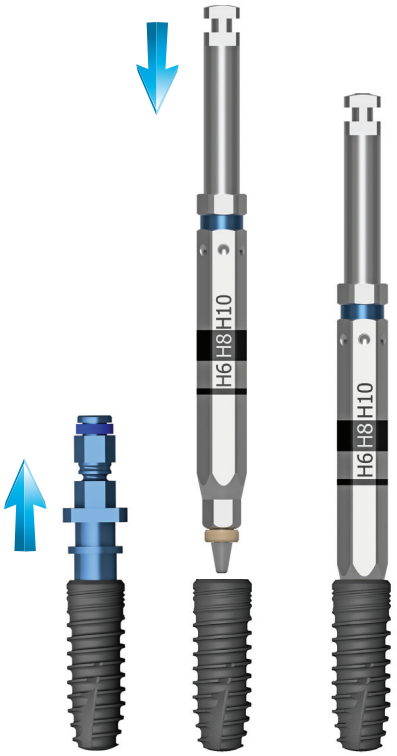


Instructions

Consult the surgical protocol to determine the guide sleeve position (H6, H8 or H10). Consult the surgical protocol to determine whether the considered implant has QN or QR prosthetic platform and select the corresponding Direct Driver (GS).
Direct Drivers are color-coded according to the corresponding implant platform. Yellow color for the QN prosthetic platform, blue color for the QR prosthetic platform. The QN (Q-Lock Narrow) platform is exclusive to the S2.9 implants. The QR (Q-Lock Regular) platform is exclusive to the S3.5, S4.0/T4.0 and S5.0/T5.0 implant series.

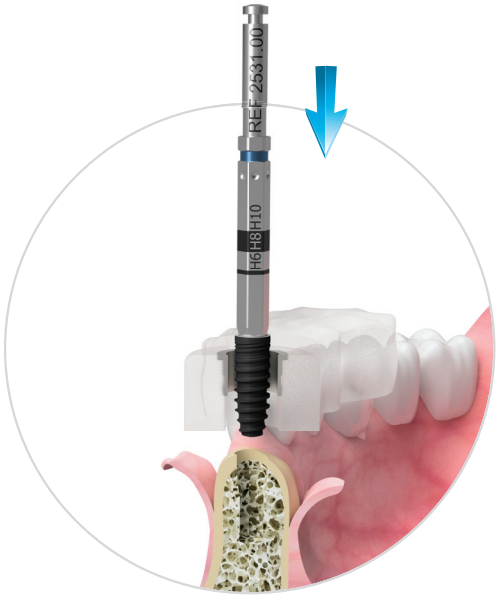
Open the implant package. The BioniQ implant package contains a sterile cover screw. To remove the implant from the inner blister, peel off the paper from the back of the inner blister to about three quarters of its length to prevent the cover screw falling out of the package. Pull out the implant from the plastic holder with help of the Insertion wrench BioniQ using a twisting motion. Pull the implant carrier out of the implant and attach the Direct Driver (GS) to the implant.
To avoid damage or contamination to the implant BIO-surface, use a tweezers to hold the implant.



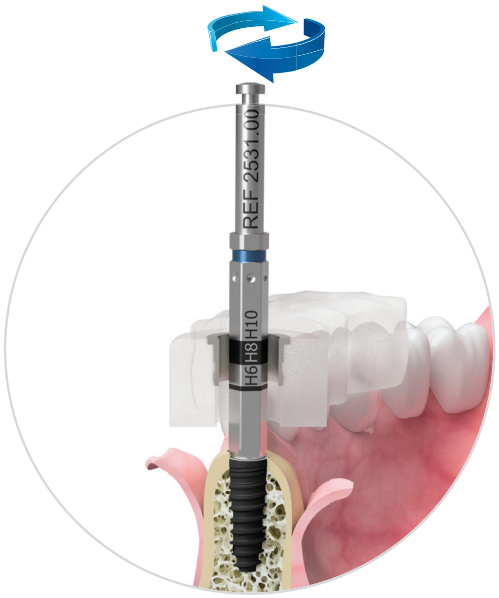


No auxiliary guide tool is used in this step.

Surgical procedure



Using the Direct Driver (GS), place the implant into the respective guide sleeve of the surgical template. Align the axis of the assembly to the axis of the guide sleeve.



Insert the implant into the bone by turning the Direct Driver (GS) slowly clockwise.

The maximum recommended insertion torque of BioniQ implants is 60 Ncm.

Exceeding the torque of 60 Ncm may result in damage of the instruments or implant's internal geometry.

Direct Driver (GS) is not equipped with a depth stop.
The depth control is managed by the laser depth marks.

Thre Direct Driver (GS) cannot be used without use of a surgical template due to differences in laser depth marks.

Pull the direct driver out of the implant.

Remove the surgical template.

Cover the implant with a cover screw or a suitable gingiva former and treat the surgical site adequately.

MAINTENANCE, CLEANING AND CARE INSTRUCTIONS

The instrument's quality and service life depends on adherence to the recommended maintenance, cleaning and care instructions. Disinfection and cleaning of the instruments must be done immediately following the instrument's use; organic residues must not be left to dry on the instruments. Use only cleaning and disinfecting agents that are recommended for surgical instruments (e.g. DENTACLEAN Instrument Plus). Cleaning agents with a high chlorine content or cleaning agents that contain oxalic acid or hydrogen peroxide are not suitable for cleaning and disinfecting stainless steel or anodized titanium alloy instruments. The use of a cleaning solution that is strong acid or strong base may damage the surface of the instruments. Follow the manufacturer's instructions when using the cleaning and disinfecting agents (in particular, comply with expiry date and recommended dilution, reaction time and temperature). Wear appropriate personal protective equipment when cleaning and disinfecting the instruments.
The surface of the instruments shall be mechanically cleaned with a soft bristled nylon brush (using metal brushes or steel wool may damage the surface of the instruments) and after that the instruments shall be placed into an ultrasonic bath. It is necessary to ensure that the instruments do not touch each other in the ultrasonic bath (e.g., with the help of appropriate organizers). Special attention should be paid to holes and cavities (a miniature soft bristled brush is suitable for cleaning them, e.g. an interdental brush). Complex instruments (e.g. ratchet) must be disassembled before cleaning. Rinse the instruments thoroughly under running water to remove all cleaning, saline and disinfectant solutions. After that the instruments must be dried. It is necessary to ensure that the instruments do not touch each other during the drying process. Do not exceed 120 °C during the drying process (too high a temperature may damage the instruments).
The recommended method for disinfecting and cleaning the instruments manufactured by the LASAK Company (validated by LASAK s. r. o.) consists of disinfection in an immersion bath for 30 minutes with a 3% solution of DENTACLEAN Instrument Plus. Drinking water at 30 °C shall be used to dilute the solution. This is followed by manual cleaning with a soft bristled nylon brush (as long as residues are visually visible on the surface) and then the instruments shall be rinsed with drinking water. The next step consists of cleaning the instruments in an ultrasonic bath (recommended parameters: frequency 35 kHz, power 180 Wef) for 15 minutes with a 1% solution of DENTACLEAN Instrument Plus at 40 °C, rinsing the instruments with drinking water and a final rinsing with demineralized water. The final step is drying in a hot air drying machine at 120 ° C for 10 minutes.
Exposure of stainless steel instruments to the saline solution for longer than necessary or evaporation of the saline solution from the surface of the instruments may lead to surface corrosion. Contact of the instruments with each other or contact with a corroded instrument during the cleaning or sterilization process may lead to surface corrosion. Mechanical or chemical damage to the surface may result in discoloration of the anodized titanium alloy instruments. The original color shade is preserved only on a clean and undamaged anodized surface. Plastic (e.g. PEEK) components of certain instruments may be damaged by excessive mechanical or thermal strain as well as by aggressive chemicals.
Cleaned and disinfected instruments shall be kept dry in between sub-processes (moisture may lead to corrosion of the instruments). Blunt, damaged, and corroded tools must be disposed of; further use is not permitted. Corroded instruments must not be sterilized (there is a risk of contamination of the autoclave and other instruments with rust particles and a subsequent spread of corrosion).

STERILIZATION

Sterilization of the stainless steel instruments is performed by moist heat in an autoclave (steam sterilizer); other sterilization methods are not allowed. During hot air (dry heat) sterilization, the structure of metal and plastic materials may be damaged, which leads to a lifetime reduction of the instruments. Furthermore, the plastic cassette must not be sterilized by hot air (dry heat), since high temperature may damage the cassette. Chemical sterilization may damage the structure of the materials of the instruments and, therefore, is not permitted.

Sterilization in cassette

Sterilization of the surgical instruments in an autoclave is performed in a plastic cassette, which is part of the BioniQ system. Pay attention to the correct placement of the sterilization cassette in the autoclave – the cassette should be placed in the centre of the autoclave and must not touch its walls.

Sterilization in sterilization pouches

Another option is to sterilize the instruments in sterilization pouches (paper or plastic packaging that meets the requirements of ČSN EN ISO 11607-1 and ČSN EN ISO 11607-2, e.g. Steriking®). The instruments are placed in the sterilization pouches individually, but it is also possible to place the entire cassette into one sterilization pouch. Use appropriate accessories (organizers) to ensure proper steam penetration. Before first sterilization of the instruments, remove any protective packaging from the instrument (sterilization is allowed only in the primary package that is the sterilization pouch).
The recommended steam sterilization method for LASAK stainless steel instruments (validated by LASAK s. r. o.) is at 134 °C (exposure time 10 minutes). A higher sterilization temperature than the recommended may damage that instruments. Appropriate programs containing a drying phase of sufficient length must be used for the sterilization of instruments in a sterilization pouch (keeping instruments in a moist sterilization pouch may cause corrosion).

Warnings

Any other method of stream sterilization (besides the recommended options) is unacceptable (unpacked loose components, components touching each other, etc.). It is recommended to sterilize stainless steel instruments separately from instruments made of other materials. Sterilization of titanium alloy instruments in the cassette together with other (stainless steel) instruments is permitted provided that the instruments do not touch each other. Do not exceed the maximum load of the sterilizer.
Sterilized instruments shall be kept in sterilization pouches (protection against subsequent microbial contamination) at room temperature, and in a dry, dust-free and disinfected place. Packages containing sterilized instruments must show the date of sterilization and expiration. If the sterilization period has expired, the instruments should be re-sterilized. The sterilization cycle shall be monitored and documented in accordance with the corresponding regulations.
The ratchet must be disassembled prior to disinfection and cleaning. Sterilization of the assembled ratchet is allowed (typically placed in the cassette). The ratchet is reassembled after all of its elements are completely dry.
When sterilizing instruments, follow the instructions from the sterilizer manufacturer and proceed in accordance with the current national and international legislation.
In no event shall LASAK be liable for sterilization of the medical devices, regardless of who has carried out sterilization or by which method.

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