

Procedures manual



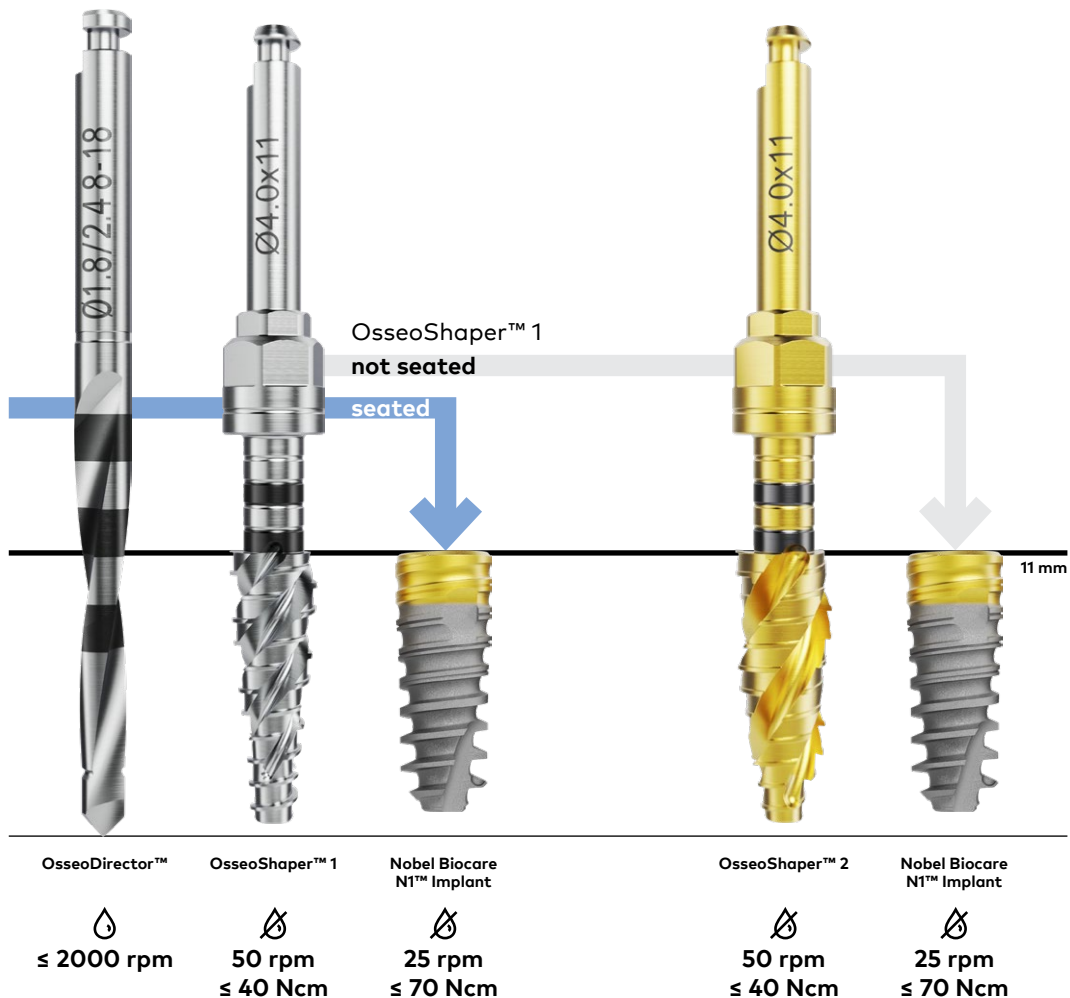
**Nobel Biocare N1™**

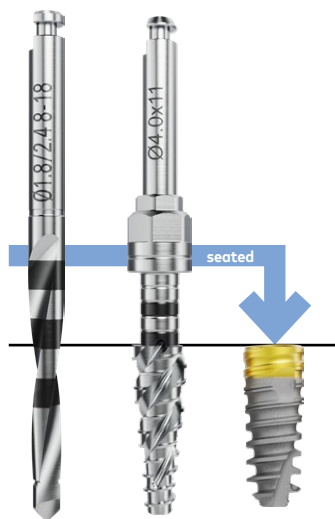
# Surgical PROCEDURE

# Surgical workflow overview

The osteotomy is created using either the OsseoDirector or Guided Pilot Drill, and OsseoShaper instruments. The OsseoShaper instruments are threaded devices that are inserted and removed at low speed without irrigation. They allow the clinician to replace the usual drills used for the creation of the osteotomy.

Below demonstrates the surgical protocol based on the Nobel Biocare N1 RP 4x11 mm implant.





## OsseoShaper™ 1 instrument

When the OsseoShaper 1 instrument has reached the planned position within the torque value of 40 Ncm then the implant can be placed. Otherwise the OsseoShaper 2 instrument needs to be used.



## OsseoShaper™ 2 instrument

When the OsseoShaper 2 instrument has reached the planned position within the torque value of 40 Ncm then the implant can be placed. Otherwise the Twist Step Drill needs to be used.



## Twist Step Drill

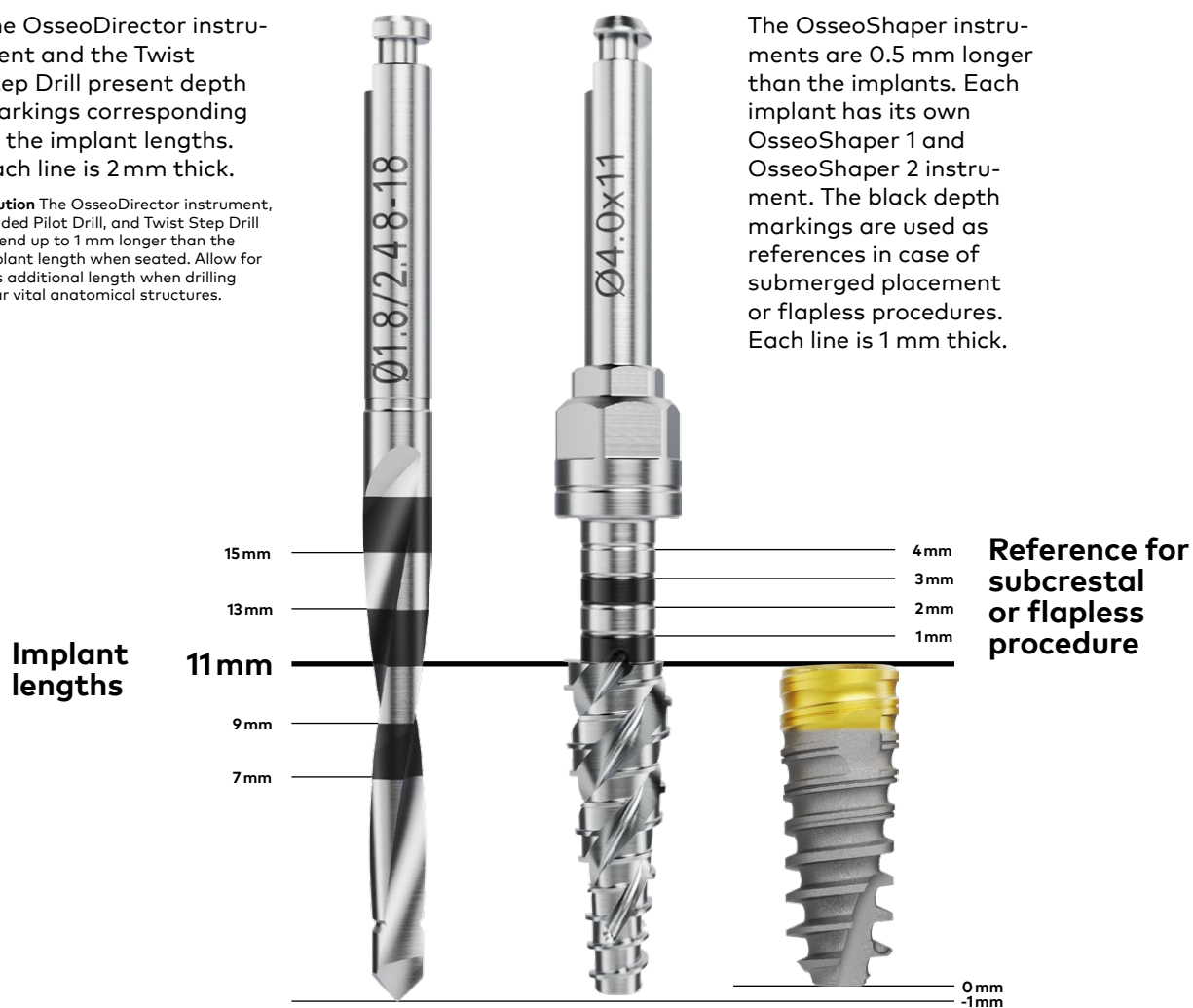
The Twist Step Drill is used with the same parameters used for the OsseoDirector ( $\leq 2000$  rpm, constant and profuse irrigation).

# Depth markings

The OsseoDirector instrument and the Twist Step Drill present depth markings corresponding to the implant lengths. Each line is 2 mm thick.

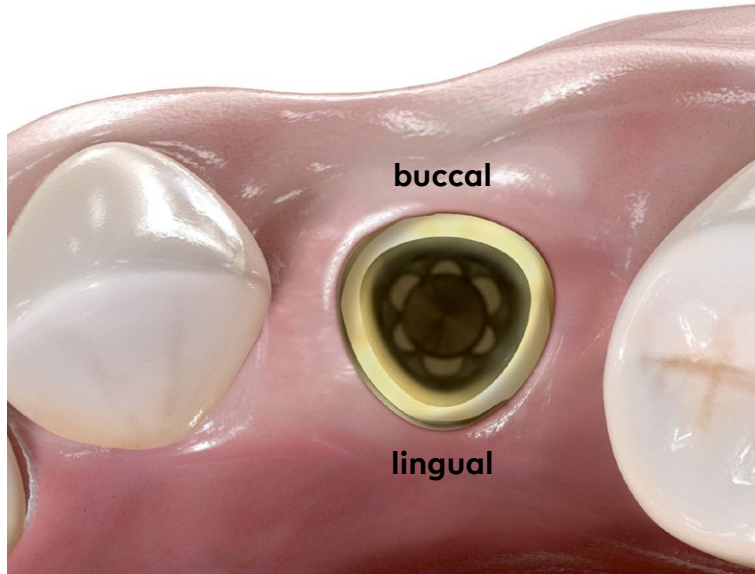
**Caution** The OsseoDirector instrument, Guided Pilot Drill, and Twist Step Drill extend up to 1 mm longer than the implant length when seated. Allow for this additional length when drilling near vital anatomical structures.

The OsseoShaper instruments are 0.5 mm longer than the implants. Each implant has its own OsseoShaper 1 and OsseoShaper 2 instrument. The black depth markings are used as references in case of submerged placement or flapless procedures. Each line is 1 mm thick.





# Surgical considerations



## **Implant positioning**

The implant should be positioned so that the flat side of the tri-oval shape faces buccally to maximize buccal wall volume at the time of implant placement.

Use the Manual Torque Wrench Surgical to adjust the final implant positioning. In cases where this is not possible, proceed with the restorative workflow options considering the abutment orientation.

# Osseo-Director™ instrument

The OsseoDirector instrument is the first device in the Nobel Biocare N1 site preparation protocol, and it defines the final implant position.



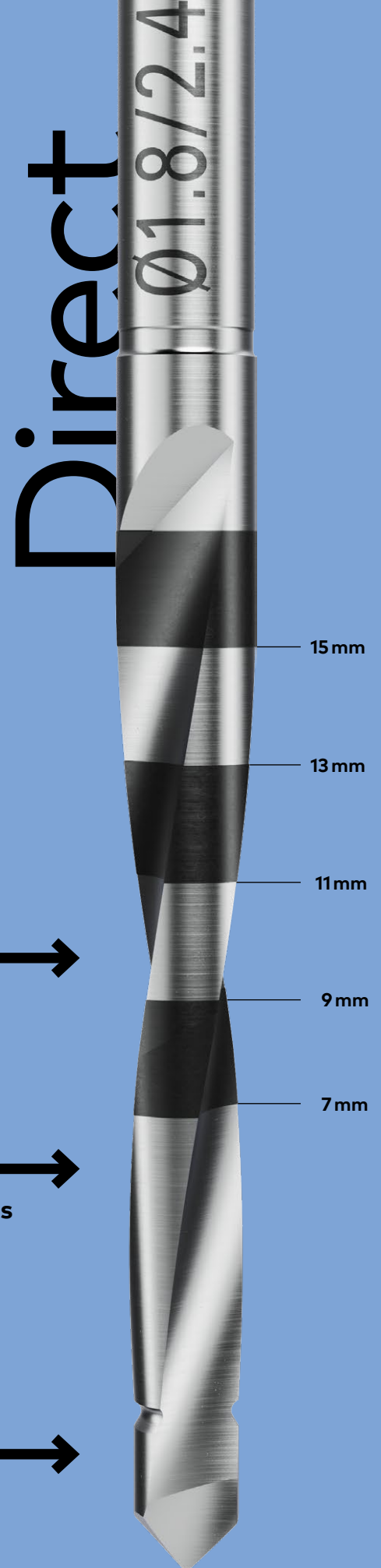
Depth  
markings



Cutting flutes  
and tapered  
body



Sharp tip



1

The OsseoDirector instrument must proceed at high speed, maximum 2000 rpm and under constant and profuse irrigation by sterile saline solution at room temperature.

💧 ≤2000 rpm



It's important to drill until the full depth in order to successfully prepare the site for the implant.

**Caution** The OsseoDirector instrument extends up to 1 mm longer than the implant length. Allow for this additional length when drilling near vital anatomical structures.

2

Prepare the osteotomy with the OsseoDirector instrument at the planned depth. In situations where adjacent natural teeth interfere with the contra-angle head, the OsseoShaper Extension can be used together with the OsseoDirector instrument.



The OsseoDirector instrument allows you to change direction and inclination while drilling.

**Warning** The OsseoDirector instrument, Guided Pilot Drill, OsseoShaper instruments and Twist Step Drills are sharp instruments. Handle with care to prevent injury.

3

You can check the orientation of the osteotomy with the Direction Indicator. The depth probe can be used to check the right depth of the osteotomy.



The Direction Indicator has two sides: the tapered side fits the osteotomy created with the OsseoDirector and the other side (straight) fits the osteotomy created with the Guided Pilot Drill.

**Note** It is recommended to use a suture thread through the hole to prevent aspiration.

**Caution** Use of the wrong depth probe can result in incorrect measurement of the osteotomy depth. The Depth Probe Nobel Biocare N1 has to be used.

# Osseo-Shaper™ 1 instrument

Developed as part of the full Nobel Biocare N1 system, the OsseoShaper instrument 'shapes' the osteotomy:

It operates at low speed – just 50 rpm.

No irrigation is required.



1

Set up the drill unit with maximum speed at 50 rpm, insertion torque at 40 Ncm and no irrigation.

⚙️ 50 rpm / 40 Ncm



**Caution** The drill unit maximum torque must be set to 40 Ncm. Exceeding 40 Ncm may damage the contra-angle and related tooling.

2

The OsseoShaper 1 instrument is delivered co-packed with the respective implant. Engage the OsseoShaper 1 instrument with the contra-angle directly from the packaging. Once it is engaged, push the white fingers and gently pull out the OsseoShaper 1 instrument.



3

Insert the OsseoShaper 1 instrument by drilling forward direction to the defined depth or until it prematurely stops. Remove by setting the reverse direction at 50 rpm and without irrigation.



In situations where adjacent natural teeth interfere with the contra-angle head, the OsseoShaper Extension can be used together with the OsseoShaper 1 instrument.

Allow the OsseoShaper 1 instrument to feed in without applying pressure, it will follow the osteotomy created by the OsseoDirector instrument.

\*

When the OsseoShaper 1 instrument has reached the planned position within the torque value of 40 Ncm then the implant can be placed (see [page 14](#)). Otherwise the OsseoShaper 2 instrument needs to be used (see [page 10](#)).



**Warning** Do not apply excessive forces while using the OsseoShaper 1 instrument to avoid injuring underlying vital structures.

**Caution** Do not pull the OsseoShaper 1 instrument out from the osteotomy without setting the reverse turning mode to avoid damaging the osteotomy.

**Caution** Ensure the OsseoShaper instrument is fully inserted in the contra-angle. The OsseoShaper instrument may become stuck if incorrectly assembled. Using the OsseoShaper instrument at speeds greater than 50 rpm may damage your contra-angle, tooling or the bone.

**Caution** Never exceed insertion torque of 40 Ncm for the OsseoShapers. Overtorquing of the OsseoShaper instrument may lead to fracture or necrosis of the bone, to damage the tooling such as contra-angle or drill extension.

**Caution** Exceeding maximum recommended torque might cause the OsseoShaper 1 instrument to get stuck in the OsseoShaper Extension.



# Osseo-Shaper™ 2 instrument

The OsseoShaper 2 instrument is used with the same parameters (speed and insertion torque) used for the OsseoShaper 1 instrument.



1

Select the OsseoShaper 2 instrument size that corresponds to the implant length and diameter. The OsseoShaper 2 instruments are color coded based on the implant diameter: magenta for implant diameter 3.5 mm and yellow for implant diameter 4.0 mm



2

Set up the drill unit with maximum speed at 50 rpm, insertion torque at 40 Ncm and no irrigation.

⚡ 50 rpm / 40 Ncm

**Warning** Do not apply excessive forces while using the OsseoShaper 2 instrument to avoid injuring underlying vital structures.

**Caution** Ensure the OsseoShaper 2 instrument is fully inserted in the contra-angle. The OsseoShaper 2 instrument may become stuck if incorrectly assembled. Using the OsseoShaper 2 instrument at speeds greater than 50 rpm may damage your contra-angle, tooling or the bone.

**Caution** Never exceed insertion torque of 40 Ncm for the OsseoShaper instrument. Overtorquing of the OsseoShaper instrument may lead to fracture or necrosis of the bone, to damage of tooling such as contra-angle or OsseoShaper Extension.

**Caution** The drill unit maximum torque must be set to 40 Ncm. Exceeding 40 Ncm may damage the contra-angle and related tooling.

**Caution** Exceeding maximum recommended torque might cause the OsseoShaper 2 instrument to get stuck in the OsseoShaper Extension.

3

Insert the OsseoShaper 2 instrument by drilling forward direction at 50 rpm without irrigation, and remove by setting the reverse direction at 50 rpm and without irrigation.



In situations where adjacent natural teeth interfere with the contra-angle head, the OsseoShaper Extension can be used together with the OsseoShaper 2 instrument.

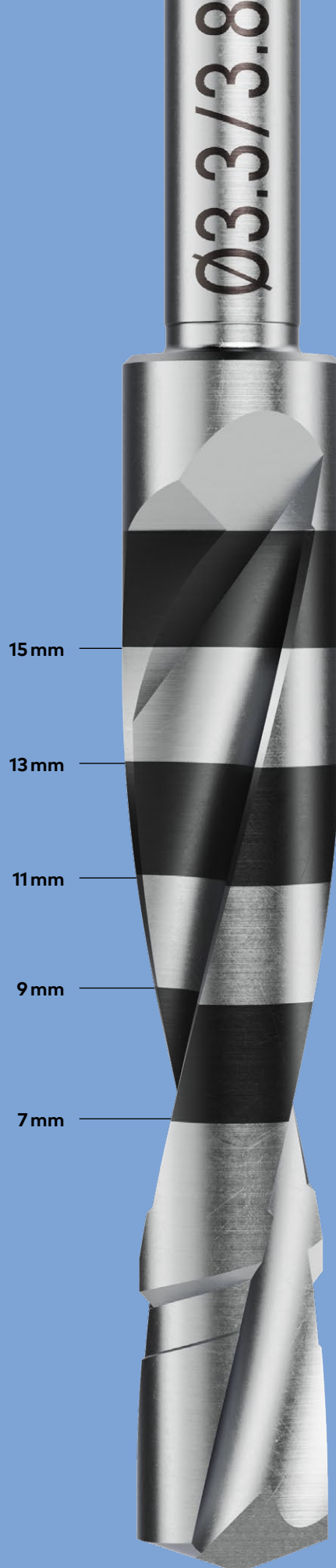
Allow the OsseoShaper 2 instrument to feed in without pressure to the defined depth or until it prematurely stops.

\*

When the OsseoShaper 2 instrument has reached the planned position within the torque value of 40 Ncm then the implant can be placed (see [page 14](#)). Otherwise the Twist Step Drill needs to be used (see [page 12](#)).

# Twist Step Drill

The Twist Step Drill should be used only in cases where the implant cannot be placed at the planned depth after the OsseoShaper 2 instrument.



1

Select the Twist Step Drill that corresponds to the implant diameter.

2

Set up the drill unit at high speed, maximum 2000 rpm, with irrigation and engage the Twist Step Drill to the handpiece.

💧 ≤2000 rpm



3

Drill forward at the planned depth in order to widen the osteotomy. In situations where adjacent natural teeth interfere with the contra-angle head, the OsseoShaper Extension can be used together with the Twist Step Drill.



\*

You can now proceed with the implant placement (see [page 14](#)).

# Implant placement

1

Rotate upside down the implant packaging and remove the white case from the titanium sleeve.



2

Use the Nobel Biocare N1 Implant Driver to pick up the implant from the titanium sleeve.

Set up the drilling unit with maximum speed at 25 rpm and maximum insertion torque at 70 Ncm.

25 rpm / 70 Ncm



To engage the implant, hold the titanium sleeve and slowly rotate the implant driver, it will automatically engage the implant.

3

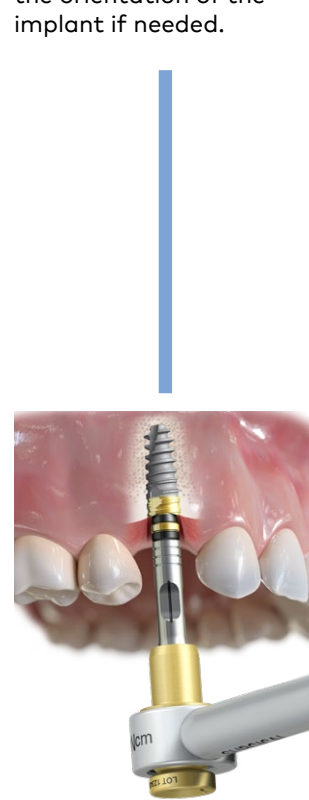
Insert the implant using the contra-angle proceeding forward at 25 rpm without irrigation.



When placing the implant, visually check that the top of the implant is positioned such that one of the flat sides faces buccally in order to maximize the space for the buccal bone volume.

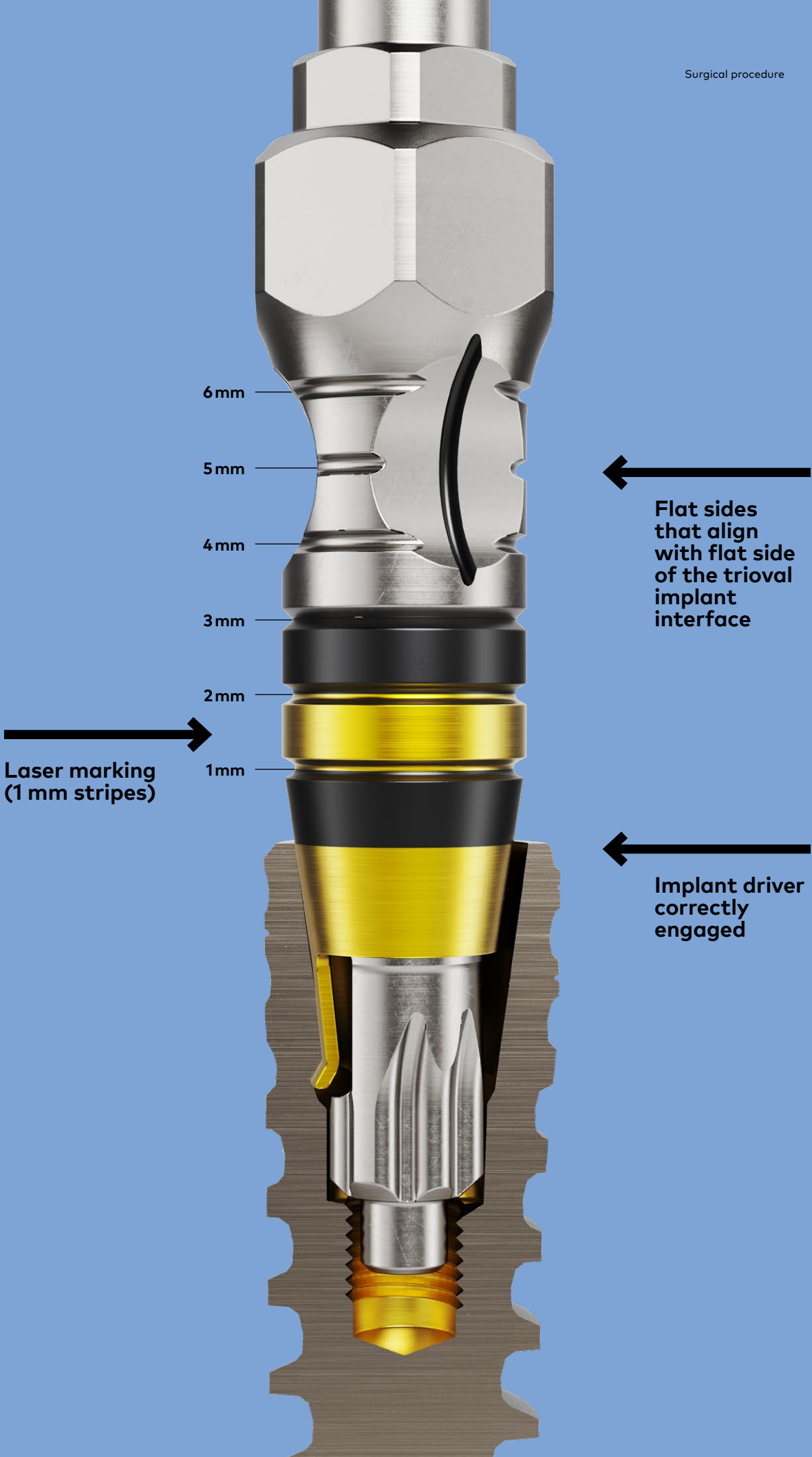
4

The Manual Torque Wrench Surgical can be used for the final placement or to correct the orientation of the implant if needed.



**Caution** Never exceed insertion torque of 70 Ncm for the implant. Overtightening an implant may lead to damaging it, fracture or necrosis of the bone site. If a surgical driver is used to insert the implant, special care needs to be taken to avoid overtightening. For immediate loading the implant should withstand a final insertion torque of at least 35 Ncm. If this insertion torque value is not achieved, other loading protocols may be considered in accordance with the Instructions For Use of the device.





---

### Order online

Order our complete range of implants and prefabricated prosthetics 24 hours a day through the Nobel Biocare online store.

[nobelbiocare.com/store](https://nobelbiocare.com/store)

---

### Order by phone

Call our customer service team or contact your sales representative.

---

### Lifetime warranty

The warranty covers all Nobel Biocare implants including prefabricated prosthetic components.

[nobelbiocare.com/warranty](https://nobelbiocare.com/warranty)



#### Manufacturer

Nobel Biocare AB Box 5190, 402 26  
Västra Hamngatan 1  
411 17 Göteborg Sweden  
[www.nobelbiocare.com](https://www.nobelbiocare.com)

#### Distributed in USA by

Nobel Biocare USA, LLC  
22715 Savi Ranch Parkway  
Yorba Linda, CA, 92887 USA

**Caution** Federal law restricts this device to sale by or on the order of a licensed physician or dentist

**Note** In order to improve readability, Nobel Biocare does not use <sup>™</sup> or <sup>®</sup> in the running text. By doing so, however, Nobel Biocare does not waive any right to the trademark or registered mark and nothing herein shall be construed to the contrary.

**Disclaimer** Some products may not be regulatory cleared, released or licensed for sale in all markets. Please contact the local Nobel Biocare sales office for current product assortment and availability.



[nobelbiocare.com/n1](https://nobelbiocare.com/n1)



GMT 79719 GB 2204 © Nobel Biocare Services AG, 2022. All rights reserved. Disclaimer: Nobel Biocare, the Nobel Biocare logotype and all other trademarks are, if nothing else is stated or is evident from the context in a certain case, trademarks of Nobel Biocare. Please refer to [nobelbiocare.com/trademarks](https://nobelbiocare.com/trademarks) for more information. Product images are not necessarily to scale. All product images are for illustration purposes only and may not be an exact representation of the product. Some products may not be regulatory cleared/released for sale in all markets. Please contact the local Nobel Biocare sales office for current product assortment and availability. Caution: Federal (United States) law or the law in your jurisdiction may restrict this device to sale by or on the order of a dentist or a physician. See Instructions For Use for full prescribing information, including indications, contraindications, warnings and precautions.

Rev 02 Date 28/04/2022