surgical protocol

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1. General considerations on the Toltac® system

The Toltac® system, like any other type of guided surgery, is designed to assist the surgeon during surgery by making it safer and more predictable and removing as much stress as possible for the operator and patient. In particular, the Toltac® system, by allowing visibility of the operating site similar to that in freehand surgery, helps the surgeon to focus on the detailed aspects (depth of the implant, management of bone and soft tissue profiles, etc.) that can lead to an increase in the quality of the performance: this makes the Toltac® system an important tool at the service of the clinician who intends to provide the patient with high quality performance. Reducing to testing the template during surgery to save a session may confront the surgeon with problems that may prevent the operation in Toltac® mode or make it more complicated and risky. Therefore: ***testing the template before surgery on the model and on the patient is absolutely compulsory to proceed with surgery according to the Toltac® protocol.***

2. Operation of the Toltac® service

Before performing patient CBCT, download the Toltac® data acquisition protocol from www.toltac.net. To take advantage of the service for the production and supply of surgical templates according to the Toltac® system, simply send the DICOM 512 x 512 data of the CBCT and the optical scans required by the Toltac® protocol to the HCS Italia s.r.l. portal (https://www.HCS Italia s.r.l.-italia.it/). The data is verified by our consultants and the customer is then notified as to whether or not it complies with the protocol; if it is deemed compliant, payment in advance for the service begins the implementation of the treatment plan. Once the plan is finalised, the consultant contacts the clinician to share the plan (via video call or via PDF file sent by email) and obtain the client's acceptance. At this point, the template is sent for production by 3D printing and equipped with the necessary Toltac® guides. If fixing pins are used, the customer must inform us whether or not they have the appropriate sliding bushings and, if so, the type and brand of these. If it does not have them, HCS Italia s.r.l. shall propose a separate sales quotation for these additional items or suggest how to obtain them directly from the respective suppliers.

3. Check of surgical instrumentation and compatibility with the Toltac® system

In principle, the Toltac® system permits the use of any type of surgical bur in guided surgery. However, a prerequisite for use of the system is that the drill has a free shank portion outside the handpiece head that is long enough to accommodate the Toltac® driver collar (thickness 2.55 mm) between the handpiece and the working part of the drill without friction on the handpiece. Most implant drills have a sufficient shank length for use with the Toltac® system, but it is advisable to carry out this check on the surgical drills at your disposal before planning your first operation with the Toltac® system to ensure that the surgical handpiece and drills will allow it to function. Some surgical handpieces have a protruding bushing that eliminates the availability of burr shank: if necessary, HCS Italia s.r.l. can supply surgical handpieces suitable for this purpose. In general, the longer the collar of the Toltac® drivers, the firmer the bur

guide. The collar of a driver can possibly be shortened by the user to allow burs with shank lengths lower than 2.55 to be adapted. Any shortening should preferably be made on the side from which the slide is longer.
NOTE: Measure the drills of a given implant system one by one, because not all of them necessarily have the same available shank length. Always measure them with the handpiece that will be used for surgery. HCS Italia s.r.l. is available for assistance at this stage.

4. Testing the surgical template on the model

Once the planning has been completed and the surgical template printed, the accuracy of the template must be tested to ensure that it has been printed correctly. The templates made according to the Toltac® protocol have numerous inspection windows that allow the clinician to check that the template's fit is accurate over the entire base, whether dental, mucosal or mixed. During the fitting test on the model, it is normal that some minor adjustments are needed to remove small smears from the template if the template does not fit properly on the model. It is also possible to mill any non-core parts of the template to further increase intraoperative visibility, if desired.
NOTE. If the template does not fit on the model despite some retouching, there may have been a problem with the printing or scanning of the model: in this case, report the problem to HCS Italia s.r.l., which will make its assistance service available to the customer.

5. Intraoral testing of the surgical template

At this point the clinician tests the accuracy with which the template sits in the patient's mouth and if necessary makes any small adjustments to improve it.
NOTE: If the template sits well on the model but does not fit properly in the mouth, it means that there have been problems in taking the impression (e.g. loose teeth, dragging of impression material...). The service department is also available to find a solution for this type of problem.
Trials of the template on the model and in the patient's mouth prior to surgery are absolutely necessary to carry out the procedure according to the Toltac® protocol.

6. Preparation of the template for surgery

The surgery can then be carried out when stated by the clinician, after cold sterilisation of the template.

7. Preparation for use of Toltac® surgical material

Proceed with an off-mouth test of the Toltac® devices by sliding the chosen drivers several times into the guides attached to the template. This will allow you to familiarise yourself with the procedure and to ensure that the sliding is such that normal surgical procedures can be carried out, eliminating any interference between the handpiece head and the template with a bur. Familiarising yourself with the insertion of the drivers into the guides outside the mouth helps you perform the operation more easily during surgery. It is very useful to practise visually looking for parallelism between the drill and the Toltac® guide before inserting the driver into the guide. Toltac® guides and drivers are made of PEEK (polyetheretherketone) certified for medical use. They are cold or autoclavable. They can withstand a sterilisation temperature of 134°C, but as with all plastic materials it is preferable, if possible, to sterilise them at 121°C or cold. The guides are intended for single-patient use, while drivers can be used up to 10 times, but more frequent turnover is recommended. The 3D-printed templates are made of laser-cured PMMA, have a CE declaration of conformity as custom-made medical devices and are cold sterilisable. They are supplied with the necessary Toltac® guides.

8. Use of the surgical template and preparation of the surgical site

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Fix the template in the patient's mouth by carefully checking its correct positioning through the inspection windows, drill the holes for the insertion of the fixation pins and apply them, if required. Prepare the surgical flap or flapless access as desired.
If desired, the flaps can be attached to the template with a suture and allow for 'hands-free' flap retraction, in which case care should be taken to disconnect them from the template if the latter needs to be removed. If, on the other hand, a flapless operation has been planned, the bur-mucotome can also be guided with Toltac®.
NOTE: With the Toltac® system, in some cases it is also possible to carry out semi-flapless surgery, i.e. by opening and removing a very small vestibular flap and removing with the mucotome the residual lingual lingual portion of gingiva at

the implant site, without performing any lingual removal. This can allow the desired amount of gingiva adhering vestibularly to the implant to be maintained, while radically reducing the invasiveness of the surgery on the lingual side. As in any type of guided surgery, the operator and assistant must constantly monitor the correct positioning of the template. If no fixation pins are provided and applied, it is sometimes sufficient for the assistant to simply hold a finger on the template to keep it in position, and/or for the surgeon himself to do so.

9. Preparation of the implant socket with the help of Toltac® system

Prepare the implant site according to the drill sequence provided by your implant system or customised protocol. In general, it is advisable to mark the position of each planned implant on the surface of the bone by directing an aiming drill (e.g. a rosette drill, spear drill, etc.) with a unidirectional Toltac® driver (preferably 5.5 mm) inserted into the groove of the Toltac® guide; if a reduced oral opening does not allow the use of a unidirectional Toltac® driver, a flat Toltac® driver can be used with the necessary precautions (see chap. 10) (see below).
At this point, follow your usual surgical sequence of operation by simply attaching a Toltac® driver to the shank of each drill before using it and inserting the guide carriage into the groove of the Toltac® guides on the template. Select the Toltac® driver with the longest possible collar compatible with the free portion of the shank outside the surgical handpiece. The Toltac® driver is asymmetrical (its guide carriage has one long and one short end), so you can choose your preferred position (normal or inverted) in order to engage the Toltac® guide more or less early. You can also decide during surgery, simply by changing the orientation of the driver according to your needs, and according to the size of each individual drill used. As a general rule, prefer whenever possible to insert from the long side so as to approach the surface of the bone already enjoying a very stable guide.
VERY IMPORTANT NOTE no.1. The Toltac® System allows the use of drills equipped with a bone stop, but does NOT assist the surgeon with his own depth stop system: this means that the drilling depth of the implant site and the subsequent implant insertion depend exclusively on the surgeon's control of the drills during the processing of the implant site.
VERY IMPORTANT NOTE no. 2. The Toltac® System helps the surgeon find the planned implant site and carry out the site preparation steps, but it does not completely replace the surgeon's ability to direct the drill. This means that the surgeon must still ALWAYS maintain a certain level of directional control. In particular, at the beginning of site preparation it is important that the surgeon "mimes" the movement of marking the initial mark on the bone as the billiard player does with the cue before hitting the ball: this allows the correct axis of movement of the drill to be identified and directed in the initial stages of drilling; once the site has been marked in this way, the system will allow the surgeon greater comfort in continuing the preparation.
The* Toltac® System *helps the surgeon when preparing the planned implant site and carrying out the site preparation steps, but it does not completely replace the surgeon's ability to direct the drill. This means that the surgeon must still ALWAYS maintain a certain level of directional control. In particular, at the beginning of site preparation it is important that the surgeon "mimics" the movement of marking the initial notch on the bone as the billiard player does with the cue before hitting the ball: this allows the correct axis of movement of the drill to be identified and directed in the initial stages of drilling; once the site has been marked in this way, the system will allow the surgeon greater comfort in continuing the preparation.
In order to increase the precision and operating comfort of the procedure, it is very useful that a finger of the surgeon's hand not holding the handpiece is used to push the handpiece head and/or the part of the* Toltac® driver *not engaged in the* Toltac® guide*, helping it to move in an axial direction: in this way, both hands will help to hold the bur in position and facilitate its descent into the site being prepared.

10. Use of flat Toltac® driver in case of limited oral opening

If there is no space to enter the guide with a normal Toltac® driver, use a flat Toltac® driver and enter from the side, taking care to keep the sliding part of the driver constantly resting on the bottom of the guide groove. For this purpose, before starting drilling with each cutter, it is a good idea to mimic the movement by sliding back and forth in the groove to perceive the planned direction, visually checking the parallelism between cutter and guides. Especially in this case, it is important to use the two-handed grip described above. Although the flat driver only gives guidance in the mesio/distal direction and not in the buccal/lingual direction, the positioning hole previously made with the initial drill in the driver will guide the drill bit, making it easier to find and maintain the correct drill direction even with the flat driver.

11. Accuracy and clearance of the Toltac® driver

Toltac® drivers are designed to allow intimate contact of their collar with the drill's neck. The guide carriage, on the other hand, has sufficient mechanical tolerance to allow it to slide smoothly in the groove of the guide and to limit the risk of seizure when removing implant mounters.

12. Use of the Toltac® template to identify implant positions in freehand surgery

If a more superficial impact of the system on your surgery is desired, by attaching an unidirectional Toltac® driver to each guide of the template and inserting a target drill as described above, it is possible to use the Toltac® template for marking implant sites only and then proceed freehand. If the oral opening is insufficient, marking can be carried out with the flat driver as described above. Bear in mind, however, that in this case the inclination of the implant will depend solely on the inclination of the drill that is no longer guided by the system.

13. Implant insertion

This can be carried out by guiding the handpiece adapter with a Toltac® driver or, if preferred, with a freehand technique.

14. Sliding problems with components during surgery

The seizure of components during the preparation of implant sites with guided surgery is a relatively frequent occurrence, although easily solved. In the case of the Toltac® system, the presence of an intermediate structure between the drill and the guide allows easier removal of devices.
If it is difficult to remove a driver from the groove in the guide and/or the drill from the hole in the bone, attempt to remove it by turning the drill with the motor in a counter-clockwise direction, possibly with a few small jolts. If this is not enough, disengage the cutter from the handpiece, then pull the cutter out with tweezers, or push the driver with the excavator towards the exit, always bearing in mind that it is easier to pull the driver out if you apply force as close as possible to its slide in the guide.
If the jig is not pinned in place and it is not possible in any other way, the jig, cutter, driver and handpiece can be gently removed together and then easily separated from the mouth and the jig repositioned. In this case, during removal from the mouth, the template should be supported by the surgeon in order to avoid excessive twisting of the structure that could damage it.

15. Quick troubleshooting guide

problem	cause	solution
the drill's neck with the driver is not blocked by the clamp of the handpiece	limited neck's length available	1) retouch the collar of the driver just enough to get the drill engaged by the handpiece 2) if this is not sufficient, contact HCS Italia s.r.l. for the supply of a suitable handpiece
the template does not fit with the model	small print errors or small scanning errors	DO NOT FORCE THE MOULDER UP ON THE MODEL, make small adjustments with a milling cutter, especially in the interproximal areas and try again after each adjustment on the model
the template does not fit with the model despite retouching	possible incorrect scanning or printing problem	re-scan or re-print
the template fits on the model well but does not fit in the mouth	problems with the impression	retake impression
I can't insert the driver into the guide	alignment problem	1) try to correct visual alignment of cutter and Toltac® guide 2) if this is not sufficient, gently help the driver into the guide with the fingertip of the hand not holding the handpiece
I cannot get the driver out of the guide after milling	friction due to pressure on the drill by structures inside the bone that deflect it microscopically	1) reverse the direction of rotation of the drill 2) if this is not sufficient, disengage the drill from the handpiece, remove the handpiece and remove driver and drill with surgical tweezers

I cannot insert the driver into the guide because the patient does not open the mouth wide enough	limited oral opening	Use the flat Toltac® driver and insert it from the side
I cannot achieve complete descent of the drill into the implant site	e.g. particularly slipped bone ridge with lingual portion much higher than vestibular portion	Remove the short part of the driver slide with a drill
I cannot disengage the implant from the motor mounter after implant insertion	friction due to pressure on the implant from structures inside the bone that deflect it microscopically	Disengage the mounter from the handpiece, remove the handpiece, then remove the driver with surgical tweezers, then disengage the mounter from the implant

16. Legal considerations when using the Toltac® system

Every type of surgery, including implant surgery, involves risks that must be adequately known to the surgeon, who is responsible for preventing them. The aim of guided surgery is to help the surgeon placing implants in positions as close as possible to those planned. The risk to produce damages is anyway present, therefore the clinician must carefully plan and perform the implant intervention in order to prevent this risk, planning with adequate safety margins towards the patient's anatomical structures (e.g. alveolar nerves, maxillary sinuses, nasal fossae, dental roots...), use the devices of the Toltac® system and in general those for implant surgery only after having acquired the necessary technical preparation, and carry out the operation following the specific recommendations of the manufacturers of the devices, including that of carefully testing the template and other devices before the operation to ensure that they correspond perfectly to the specifications required for the operation and guarantee an adequate level of safety.
In spite of the use of guided surgery, the responsibility in case of possible damages remains always and only with the clinician, even if the planning of the intervention has been delegated to others: as for all guided surgery systems available on the market, in fact, the clinician in accepting the planning of the intervention according to the Toltac® system and in using the template provided, automatically assumes total responsibility for the intervention, discharging HCS Italia s.r.l, the owner of the Toltac® trademark and patent and all the operators involved in the production chain of the Toltac® system (planners, component manufacturers, 3D printers, dental technicians, etc.) from any liability for any problems during the operation or as a result of it due to planning errors, as well as in the case of direct and indirect damage resulting from the use of the system due to errors in design, clinical assessment of the patient or other errors.