

TECHNICAL DOCUMENTATION IN ACCORDANCE TO ANNEX VII – MDD 93/42

2ingis® Legs 3.0

Purpose: Guidance system; placed on the head of a "contra-angle" type drill, used for the placement of dental implants using an individual 2ingis® surgical guide.

1.Product description:

The product (guidance system) is used to guide a "contra-angle" type drill used when placing dental implants with an individual 2ingis® surgical guide.

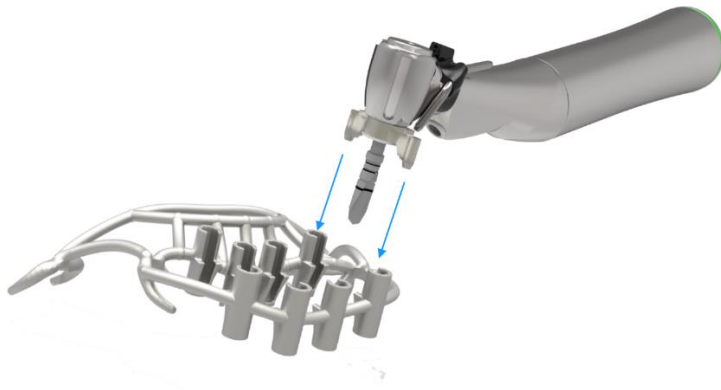
The 2ingis® Legs 3.0 is a piece that is fixed on the head of the 2ingis® / W & H contra-angle using spring steel clips. The 2ingis® / W & H contra-angle drill rotates freely through the guide system. The two guide rods are inserted into a surgical guide to perfectly direct the drill during the procedure.

The 2ingis® Legs 3.0 consists of various factory manufactured medical steel parts which cannot be dismantled.

The 2ingis® Legs 3.0 is part of the international patent application PCT / EP2016 / 080635 - December 14, 2015.

This non-invasive guidance system is used only for the placement of dental implants using an individual 2ingis® surgical guide.

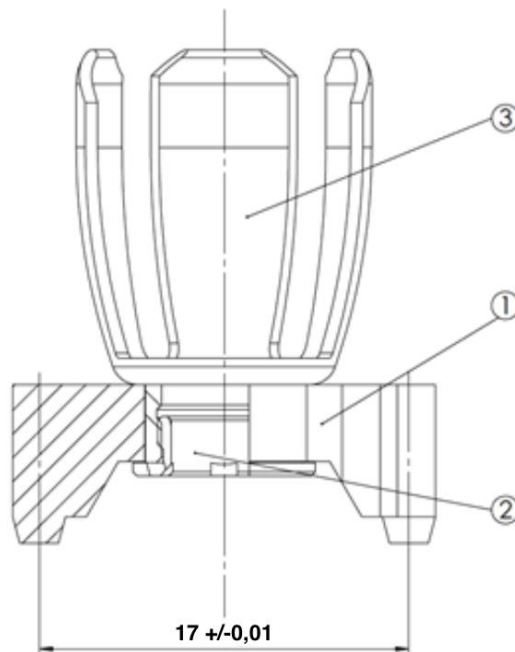
During the surgical procedure for the placement of a dental implant, the male lateral pieces are inserted into the appropriate female parts of the individual 2ingis® surgical guide placed in the patient's mouth. The pieces will guide the 2ingis® / W & H contra-angle to perform the procedure. This guides the 2ingis® / W & H contra-angle before the drill enters the patient's jawbone.



This guidance system ensures the ideal positioning (depth, axis and angulation) of the dental implant.

2. Design and manufacturing drawings:

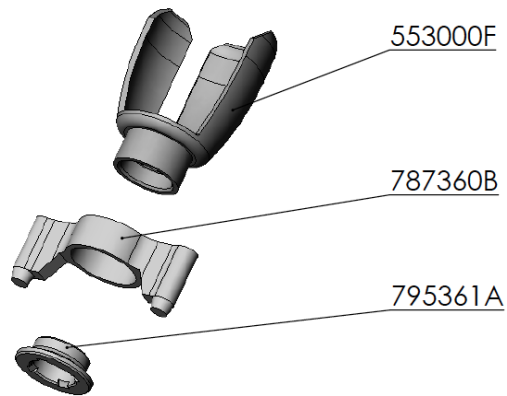
2ingis® Legs 3.0



M 2:1



Pos. Nr.:	Menge	Teile Baugr. Nr.:	Benennung
1	1	787360	UP2D Führungshülse
2	1	795361	Hohlschraube
3	1	553000	UP2D Aufsteckhülse



Teile/Baugr. Nr.:	Benennung	Menge
787360B	UP2D Führungshülse	1
795361A	Hohlschraube	1
553000F	UP2D Aufsteckhülse	1

3. Labelling and instructions for use:

The **2ingis® Legs 3.0** is delivered with its multi-language user guide (EN-FR-DE-NL) in its own non-sterile packaging.

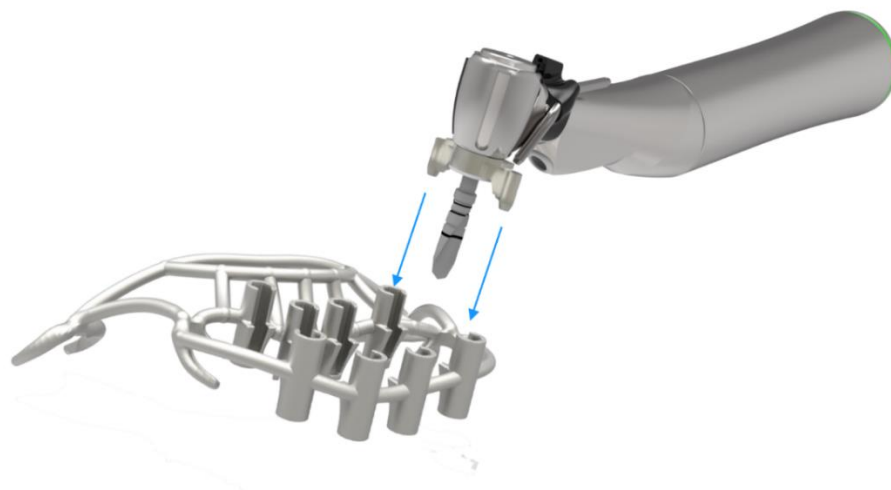
The **2ingis® Legs 3.0** is stamped with the trademark "2ingis®", the batch number, the CE mark, and the reference.

Before a surgical procedure, the product will be cleaned and sterilized.



Assembly is done by pushing the guiding system on the head of the 2ingis® / W & H contra-angle to the clip. Disassembly is achieved by simple pulling.

Instruction and diagram for the use of 2ingis® Legs 3.0 during the intervention.



The use of **2ingis® Caps 2.0** simple and is part of the commercial information for implanting dental implants with individual 2ingis® surgical guides.

The user (dental specialist) of the guidance system receives for each surgical procedure (for implant placement using a 2ingis® surgical guide) an implementation protocol in the form of a table. This protocol is indicative, individual and independent of the guidance system. It details all the stages of development of the surgical plan (type, diameter, length of the forest, position of the mouth and drilling chronology).

4. Systematic procedure for examining the data acquired on the device from production.

At the end of production, the **2ingis® Legs 3.0** is identified (marked) with a batch number of the type "SN 00000" and the CE marking.

Before packing all manufactured products undergo quality control:

- Verification of the assembled parts;
- Non-compliant parts repair;
- verification of the marking;
- Packaging.

The product ID (batch number) makes it possible to trace a series of products manufactured from the end of the production until the delivery. The batch number is part of the product label indicated on the delivery note and on the customer's invoice.

2ingis S.A. undertakes to implement the appropriate means to apply all necessary corrective measures in case of defective lot.

The **2ingis® Legs 3.0** is an external drill support that allows to guide the contra-angle and in no way penetrates partially or entirely into the tissue of the human body.

