

Instruction for use/ Product data sheet

Description of coOrdination® - system parts

The coOrdination system consists of single, double and guide sleeves made of titanium in different diameters and lengths and titanium reference balls in different diameters.

Accessories: template drills, insertion tools and sleeve holders for the titanium sleeves.

Materials:

single sleeves, double sleeves (inner and outer sleeves), guide sleeves and reference balls: pure titanium DIN 17850 (Ti4) / ASTM F67 (Grade 4)

template drills: carbide metal

insertion instruments and sleeve holders: 1.4305 steel

Notes on sterilisation and disinfection:

coOrdination sleeves and accessories are supplied non-sterile. All items with patient contact can be sterilised by the following method. Sterilisation with steam (fractionated vacuum 132/134°C, 3 bar, 5 min). Please refer to sterilisation equipment manufacturer's specifications and use validated processes only. The process described only applies to sleeves and balls. Packaging cannot be sterilised. Please refer to material manufacturer for cleaning, disinfection and sterilisation instructions for the template material used.



Notes on reusability:

Titanium sleeves and balls are made for single use on one patient only. They must not be reused! Reuse is not allowed because of cross contamination risks to patients and surgery staff. Reuse is not allowed because of risk of damage while removing the sleeves from the template plastic.



Notes on selection:

The inner diameter of the sleeves is described by the number behind the „D“ in the product REF. (e.g. M.27.03.D235 = d 2.35 mm). The titanium drilling sleeves are made to slightly exceed the nominal diameter to ensure good „drill guidance“. For example, a bur with a diameter of 2.35 mm can be reliably guided into a 2.35 mm drill sleeve (D235). Do not use burs which have too much play in the drilling sleeves as this can lead to considerable deviations from the intended drilling position

Notes on usage:

The titanium sleeves can be used for reference templates, planning and surgical templates and fully guided planning or surgical templates (guide sleeves). The titanium balls are suitable for simple planning and diagnostic templates.

Titanium planning and drill sleeves and x-ray reference balls can be placed into templates of widely differing design. Templates can be made by thermoforming, powder or milling techniques or other suitable methods. Holes can be made in the template (max. speed 1500 rpm, shank 2.35 mm) using coOrdination® system template drills to take the sleeves. As the template drill is specially made to match the outer surface geometry of the single and double sleeves, the sleeves only need to be pressed into the template. The retention notches on the outside surface of the sleeves make polymerization possible as well. To do this, the sleeve or ball is inserted into a suitable recess in the template using adhesive

The sleeves and balls are made of titanium which avoids artifacts in x-ray and CT or DVT imaging and ensures easy measurement of position and size. The geometry data can be integrated into 3D planning systems software. Pay attention to sleeve lengths when planning depth stops to match bur and implant lengths.

The fit of bur and sleeve requires checking BEFORE surgery! The surgical instrument should not jam in the sleeve or have too much play. The sleeves should be secured in the template to avoid aspiration or being swallowed during surgery. The inner sleeves can be placed onto the bur before insertion into the outer sleeve to prevent loss in the mouth.

Storage:

Dry and clean with no direct sunlight or light.

Indications:

The coOrdination implant planning system is indicated for planning and defining prosthetically, surgically and anatomically optimized implant positions and for insertion into planning and surgical templates.

Titanium reference balls can be used in simple X-ray diagnostic imaging and as reference elements in computer assisted implant planning systems.

Titanium single sleeves are indicated for pre-implant planning and simple surgical implementation of planned implant positions.

Titanium double sleeves (inner and outer sleeves) are indicated for planning and surgical drilling templates and for use in the first bur steps (e.g. pilot drill) during implant surgery. Titanium guide sleeves are indicated for use in surgical guide templates with burs which have cylindrical guide elements or which are guided into separate inserts (drill guides or handles).

Contraindications:

The titanium sleeves have cylindrical holes. For this reason they can only be used with cylindrically shaped burs or with drills with cylindrical guide faces. Conical burs cannot be led through a cylindrical sleeve and may cause jamming. Damaged or deformed titanium sleeves do not guarantee good drill guidance and must not be used. If the patient or any other person involved is allergic to the materials used in this product, they must not be used.

Description of symbols



Not sterile



Charge-
No.



Product-
Number



read the
instructions!



single
use only



manufacturer



medical product
class I acc.
GL 93/42/EWG



One simple way to surgical template



1. Production of the planning model



2. Wax up



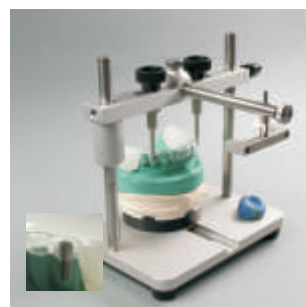
3. Duplicate model with thermoforming blank



4. Pressure moulded planning template



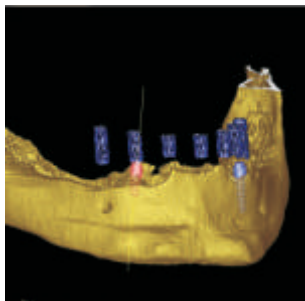
5. Fill x-ray opaque material into pressure moulded template



6. Attaching bearing sleeves - for example with the modelpositioner



7. Bearing sleeves
Alternative: Planning sleeves at each possible implant position (small picture)



8. 3D planning with software on the basis of diagnostic imaging procedures (CT, DVT, etc.)



9. Conversion of planned position to the model (for example coOrdinator®)



10. Insert sleeves into drilling template



11. Put sleeves into drilling template



Single sleeves
Inside-ø 2.35 mm
Double sleeves
Inside-ø 2.0 - 3.5 mm