flYONE®

INNOVATIVE SURGICAL GUIDE

DISCOVER THE SIMPLICITY OF FLYONE® TECHNIQUE

Transforming the CT into a real and solid replica attachable to the articulator.

INSTRUCTIONS FOR USE

Safe&Simple®

Ethical Systems for dental implantology

Safe&Simple s.r.l.
sistemi etici di implantologia dentale

1 WHAT IT IS

It is a simplified technique for applying a laser sintering model to the articulator.
It is inspired by Safe&Simple values: it is a safe and simple technique.

Main advantages:

- ✓ **Preciseness and Predictability**

It is a more precise and cheaper technique with respect of alternative solutions.
Flyone technique permits the professional to plan placement, length and diameter of the fixture before the actual surgery: in this way the surgical procedure becomes totally predictable and failure possibilities are minimized;

- ✓ **No software**

- ✓ The surgery is planned on a **solid model** which accurately reproduces:
  Maxillary bone and paranasal sinuses;
  Mandible and nerve;
  Gingiva;
  Teeth and possible avulsions.

- ✓ **Surgical template self-manufacturing**
  The professional will be able to make the surgical template on his own, with all respect of predictability and safety concepts:
  The procedure is simple and quick;
  All components get placed as they were in the mouth;
  Template precision can be evaluated immediately, as the possible need of making fixing holes;
  Tissues detachment and implants placement are planned from the prosthetic and surgical points of view;
  All components are designed according to S1 implant system, but can also fit other systems.

2 REPLICA TYPOLOGIES AND DATA TRANSFERRING CONDITIONS

Based on case features, there are 2 different types of replica: simple (type A) or suitable for articulator (type B). Also, data can be transferred through electronic transmission if the professional provide the info scan (type C).

A Simple anatomical replica

B Anatomical replica suitable for articulator

C Anatomical replica suitable for articulator with electronic transmission of models and jig

A Simple anatomical replica

code	description
MAX	Anatomical maxillary replica
MNN	Anatomical mandibular replica
MNERV	Mandibular replica with mandibular nerve
ALV	Alveolus

What has to be sent?

- ✓ Patient's CT Scan
- ✓ "Replica request" form filled up - see section 8

B Anatomical replica suitable for articulator

code	description
MAX	Anatomical maxillary replica
MNN	Anatomical mandibular replica
MNERV	Mandibular replica with mandibular nerve
MUC	Anatomical replica of mucosa
ALV	Alveolus
LFLY	Flyone processing – morphological reproduction of natural teeth and set up for articolator

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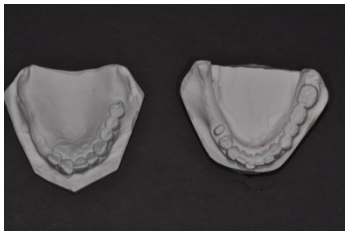
What has to be sent?

- ✓ Master and antagonist models



- ✓ Radiological template with marker

Marker Safe&Simple code NLY

- ✓ CT scan
- ✓ "Replica request" form filled up

C Anatomical replica suitable for articulator

code	description
MAX	Anatomical maxillary replica
MNN	Anatomical mandibular replica
MNERV	Mandibular replica with mandibular nerve
MUC	Anatomical replica of mucosa
ALV	Alveolus
LFLYFILE	Flyone processing – morphological reproduction of natural teeth and set up for articolator

What has to be sent through ELECTRONIC TRANSMISSION?

- ✓ Master and antagonist models
- ✓ Radiological template with marker
- ✓ CT scan
- ✓ Replica request" form filled up

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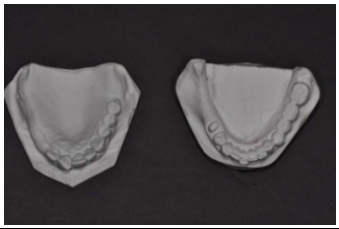
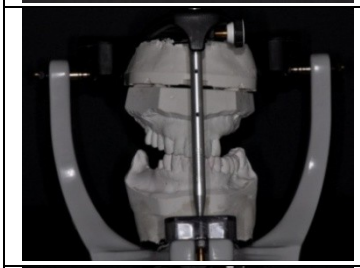
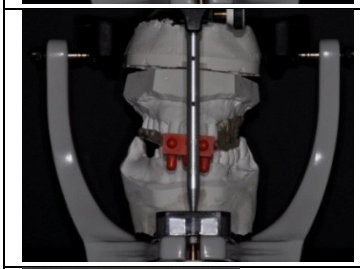
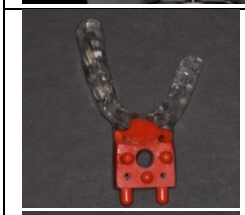
3 GYPSUM MODELS AND RADIOLOGICAL TEMPLATE (TRANSFER JIG) MANUFACTORING PROCEDURES

 	From a precision impression, we develop master and antagonist models using class IV gypsum
	The models are placed in articolation. It is important to leave the necessary space to the transfer jig to be made.
	For the template manufacturing, utilizing transparent resin for orthodontics and a Safe&Simple marker Verifying that the template is stable and intercuspidated.
 	Once polymerised the template gets refined and polished.

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4 CT SCAN ACQUISITION PROTOCOL

Images format: **DICOM**

GANTRY TILT **: 0°**

Recommended resolution: 0.250 mm

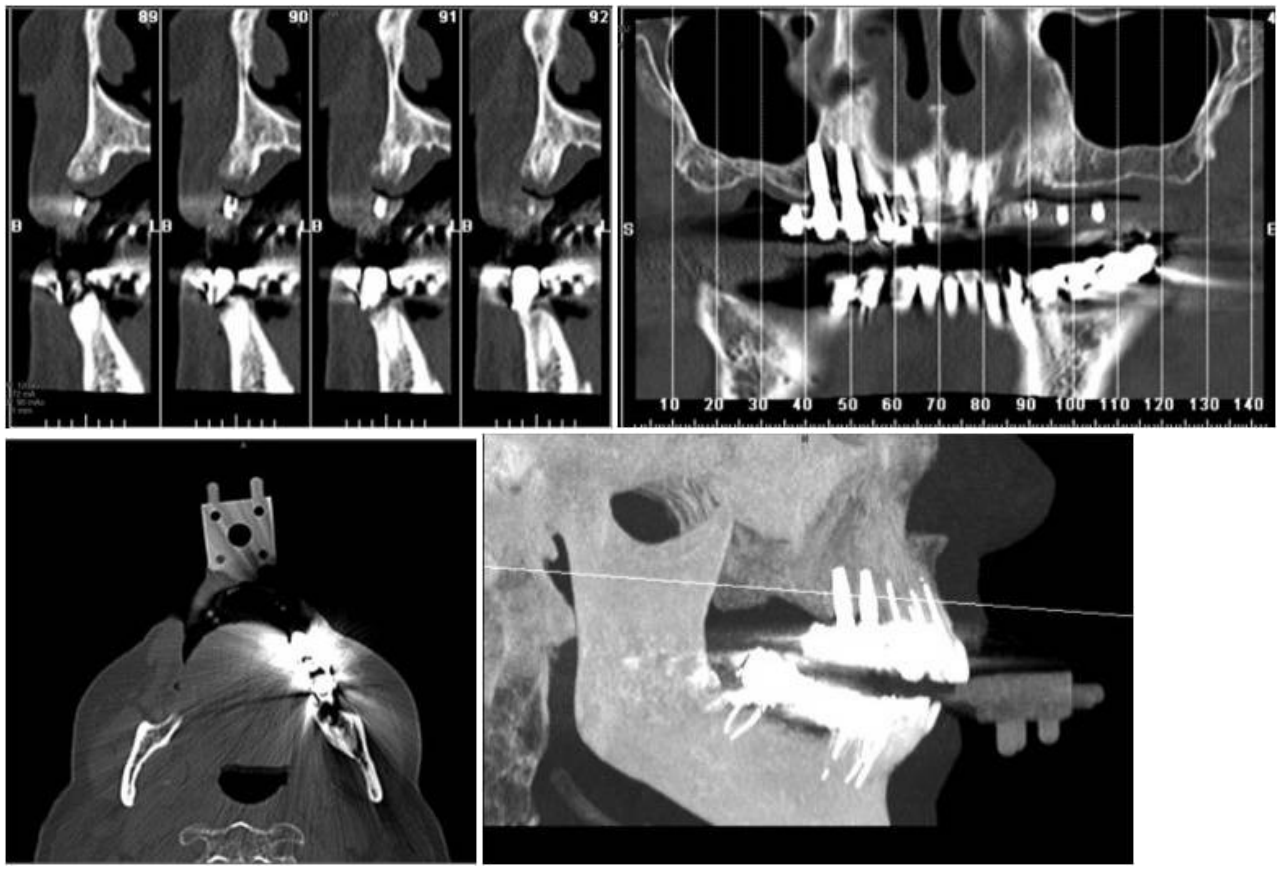
SLICES depth: as close as possible to the resolution.

Reconstruction algorithm: bone or high resolution.

It is recommended to scan the interest area only, removing, when possible, any items which could originate artifacts disturbing, covering or cancelling the anatomic part under interest.

Axial scan is sufficient when the patient is positioned making sure that the occlusal plane is parallel to the sections plane.

Illustrative images



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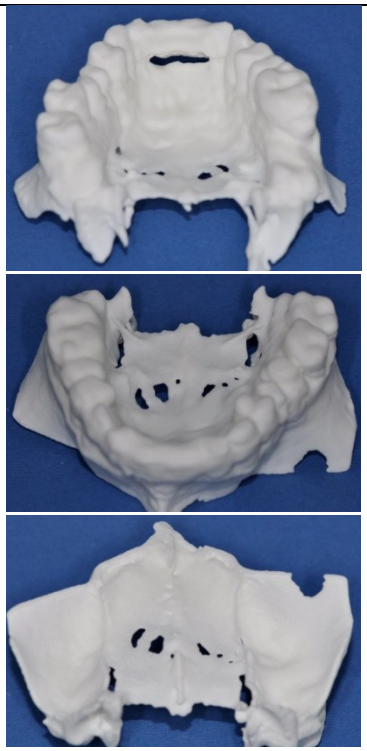
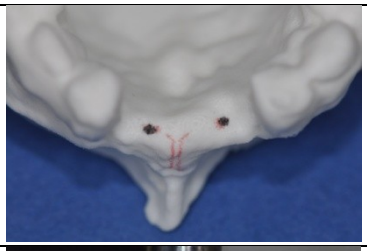
5 SURGICAL TEMPLATE MANUFACTURING PROCEDURE

A: Simple anatomical replica

	Simple stereolitographic model (A option). Images show a simple maxillary replica: palatal, vestibular and paranasal views.
	Thanks to the model, the dentist tangibly establishes where the implants will be placed in the mouth of the patient.
	The model is drilled in correspondence to the emerging decided by the dentist. The drilling procedure follows step-by-step the surgical protocol, using dedicated drills.

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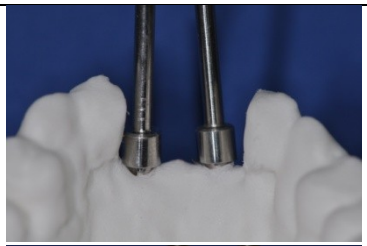
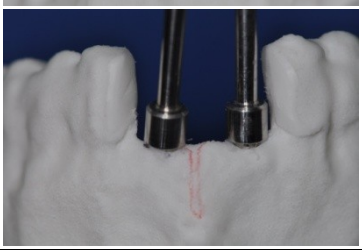
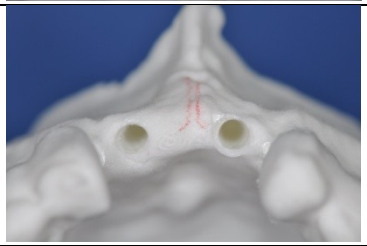
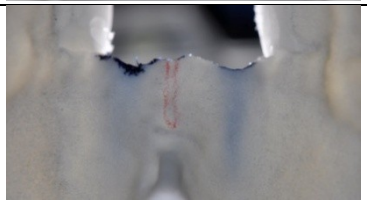
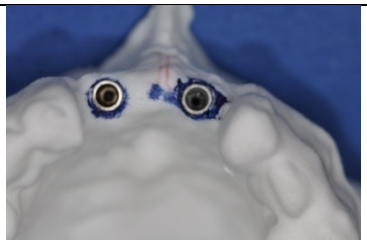
 	As shown by images (palatal and vestibular views), once the drill is placed, the dentist is able to note well emerging, abutment dimensions, implants inclination and parallelism.
	Once the holes are done, it is possible to easily establish implant diameter and length.
	The minimum bone thickness is highlighted by methylene blue.
	Implants are inserted using ratchet and ratchet driver.
	Implants are placed. At this point the dentist can tangibly evaluate the best fixture placement and dimension.

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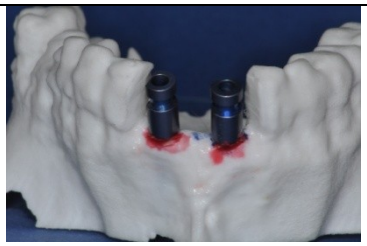
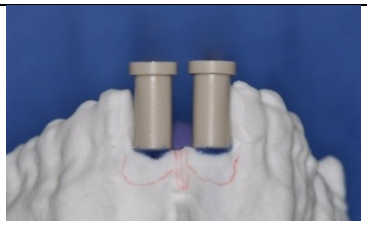
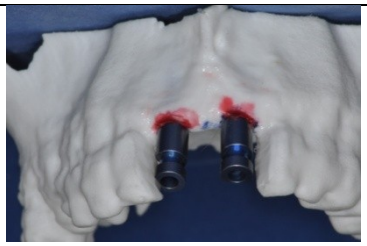
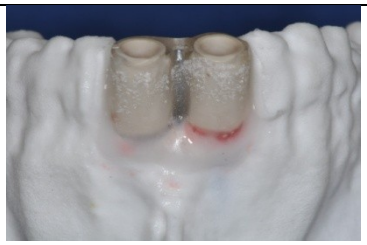
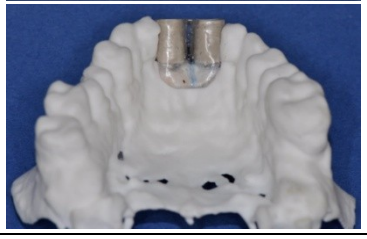
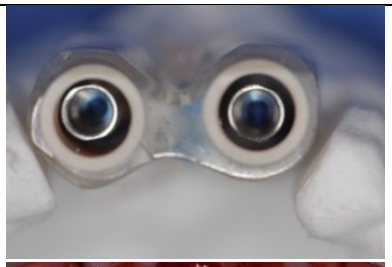
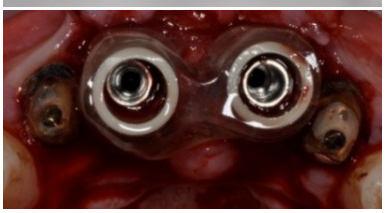
	Transfer inserts are inserted according to the fixture measure. Undercuts are eliminated through wax.
 	Ø5 supporting sleeves, which in turn contain Ø3.25 sleeves, are positioned on the transfer inserts. During the surgical phase, while placing either Ø4 or Ø5 implant, once the hole is done with pilot drill and Ø3.25 drill, Ø3.25 sleeve gets substituted by Ø4 sleeve, in order to make the use of Ø4 drill possible. If the dentist place a Ø5 implant, Ø4 sleeve will then be removed in order to allow Ø5 drill to be used. In case of Ø3.25 implant, the template can be manufactured with Ø3.25 sleeves directly, without using Ø5 supporting sleeves.
	The model gets isolated by vaseline for easing the separation between template and model.
	Resin drained.
 	The template is refined and polished (vestibular and palatal views).

 	Comparison between the template on the replica and placed in the mouth.

B/C: Anatomical replica suitable for articulator

  	Flyone stereolitographic model (B/C options). Images show a maxillary replica: palatal, vestibular and paranasal views.

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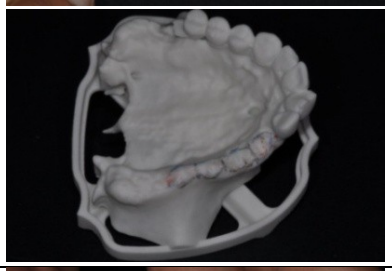
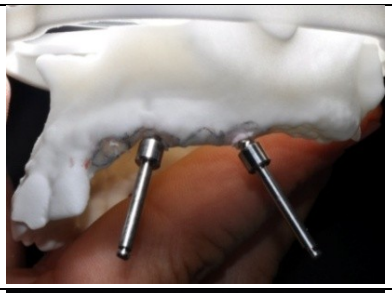
  	Diagnostic wax-up. In this way, the dentist is able to define implants placement, highlighting their emerging.
	The replica is drilled starting with the pilot drill and then with the other drills, according to the implant measure. Holes made by mistakes can be fixed with cold resin.
	The holes have been made following the bone trend, even if this entails disparallelism between the implants.
	Implants are inserted using ratchet and ratchet driver.

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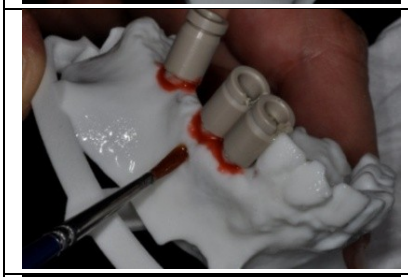
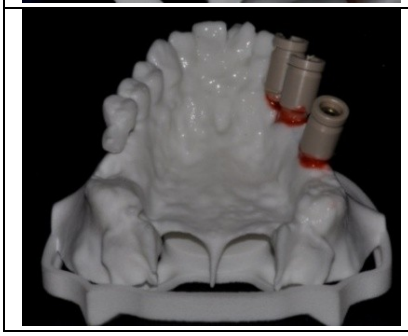
 	Transfer inserts and respective sleeves are inserted. In most of cases sleeves need to be adapted to the bone morphology.
	Once the sleeves are placed, undercuts gets eliminated through wax.
	The model gets isolated by vaseline for easing the separation between template and model.
	The replica is ready for the resin.

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	The template is made with transparent resin for orthodontics.
	Polymerised template.
	Once refined and polished, the template is ready to be transferred in the mouth.

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6 COMPONENTS CATALOGUE

KIT FLYONE code KFLYONE Containing:
1 pilot drill
11 drills Ø (3,25 L 10; Ø 3,25 L 12; Ø 3,25 L 15; Ø 4 L 8; Ø 4 L 10; Ø 4 L 12; Ø 4 L 15; Ø 5 L 8; Ø 5 L 10; Ø 5 L 12; Ø 5 L 15)
12 PEEK sleeves (4 x Ø)
12 transfer inserts (4 x Ø)
3 ratchet drivers
1 ratchet
44 fixture 4 x Ø and L. (Ø 3,25 L 10; Ø 3,25 L 12; Ø 3,25 L 15; Ø 4 L 8; Ø 4 L 10; Ø 4 L 12; Ø 4 L 15; Ø 5 L 8; Ø 5 L 10; Ø 5 L 12; Ø 5 L 15).

SINGLE COMPONENTS

Code	Description	Measure
054,01/F	drill	• L 10 Ø 3,25
054,02/F	drill	• L 12 Ø 3,25
054,03/F	drill	• L 15 Ø 3,25
053,04/F	drill	• L 8 Ø 4
053,01/F	drill	• L 10 Ø 4
053,02/F	drill	• L 12 Ø 4
053,03/F	drill	• L 15 Ø 4
055,04/F	drill	• L 8 Ø 5
055,01/F	drill	• L 10 Ø 5
055,02/F	drill	• L 12 Ø 5
055,03/F	drill	• L 15 Ø 5
060,02/F	Pilot drill	L 8
TR.325/F	transfer insert	• Ø 3,25
TR.400/F	transfer insert	• Ø 4
TR.500/F	transfer insert	• Ø 5
80022600	PEEK sleeve	Ø 3,25
80022700	PEEK sleeve	Ø 4
80022500	PEEK sleeve	Ø 5
056,02/F	long ratchet driver	• L 28 Ø 3,25
046,02/F	long ratchet driver	• L 28 Ø 4
057,02/F	long ratchet driver	• L 28 Ø 5
070,01/F	ratchet	
050,01/F	Fixture Fly	• L 10 Ø 3,25
050,02/F	Fixture Fly	• L 12 Ø 3,25
050,03/F	Fixture Fly	• L 15 Ø 3,25
040,04/F	Fixture Fly	• L 8 Ø 4
040,01/F	Fixture Fly	• L 10 Ø 4
040,02/F	Fixture Fly	• L 12 Ø 4
040,03/F	Fixture Fly	• L 15 Ø 4
049,04/F	Fixture Fly	• L 8 Ø 5
049,01/F	Fixture Fly	• L 10 Ø 5
049,02/F	Fixture Fly	• L 12 Ø 5
049,03/F	Fixture Fly	• L 15 Ø 5

7 STERILISATION PROTOCOL

Flyone® devises are provided in “non sterile” packages.
Do not use any acidic detergents; use ONLY neutral and antibacterial detergents.

CLEANING

Remove the device from the package;
Disassemble the device into its components. Please check the good state of them;
Wash the components using neutral detergent (not acidic) and warm water;
Dry with either absorbent tissue (make sure that it does not leave any residuals) , or industrial dryer or drying room.

STERILIZATION

Autoclave steam sterilization through a low temperature cycle for thermoplastic or sensible materials , (121°–125°C).
Cold sterilization using liquid with provided efficacy.

PACKAGING

Devices have to be packed preserving their sterility, using medical packing materials only.
Verify that the device once placed into the package contains is not under any stress or fatigue.

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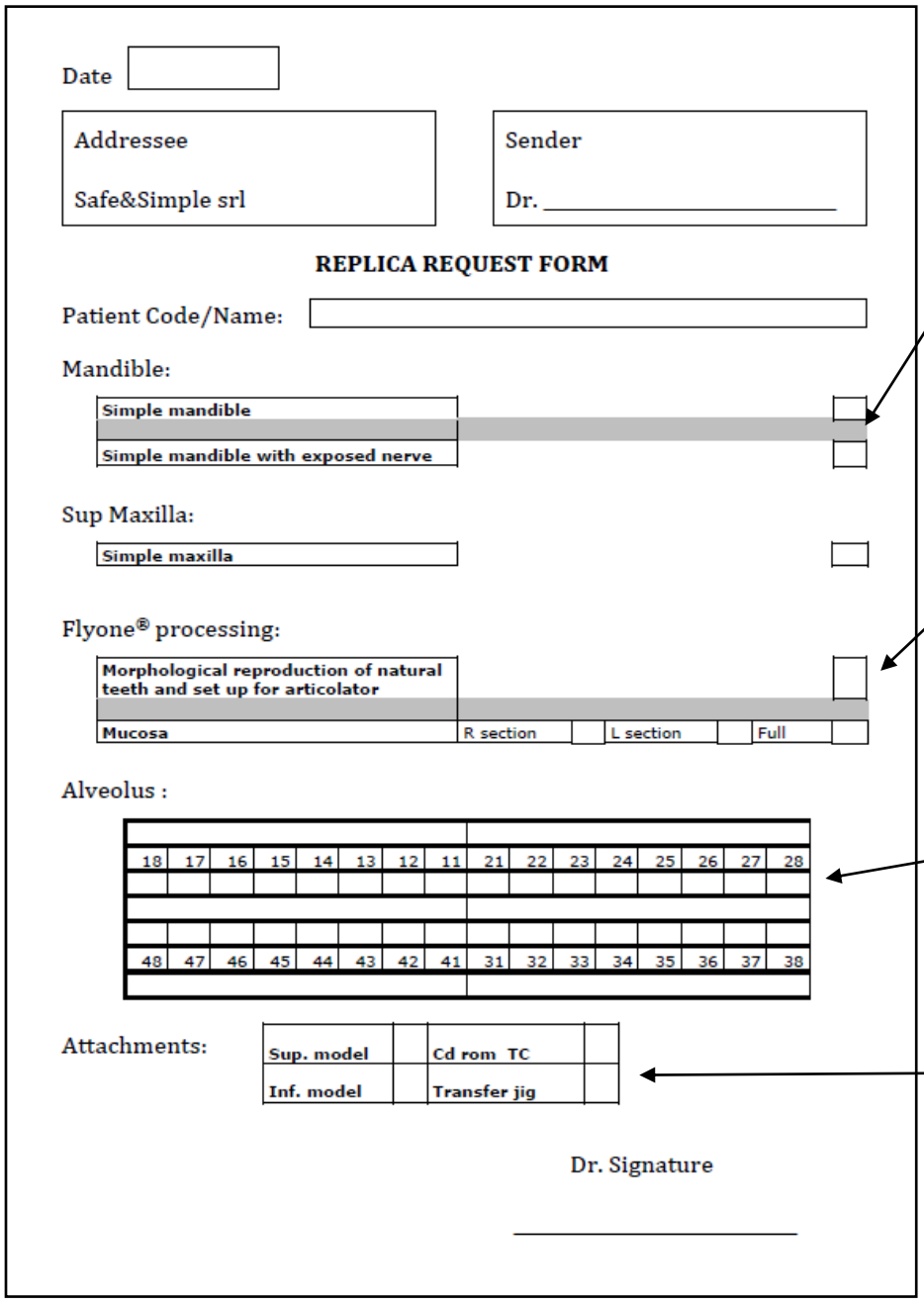
8 REPLICA REQUEST FORM



Date

Addressee	Sender
Safe&Simple srl	Dr. _____

REPLICA REQUEST FORM

Patient Code/Name:

Mandible:

Simple mandible	
Simple mandible with exposed nerve	

Sup Maxilla:

Simple maxilla	

Flyone® processing:

Morphological reproduction of natural teeth and set up for articolator					
Mucosa	R section		L section	Full	

Alveolus :

18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38

Attachments:

Sup. model		Cd rom TC	
Inf. model		Transfer jig	

Dr. Signature

_____

A) Select the replica type requested:
-mandible
-mandible with exposed nerve
-maxilla

B) Select “Flyone® processing” for a complete replica (morphological reproduction of natural teeth and set up for articulator).

C) Select any alveolus to be highlighted.

D) Select which items are attached to the form.