1 - Intended use and expected clinical benefits
The purpose of the 'Prosthetic Components' device is, by connection to the osseointegrated implant, to allow the reconstruction of the lost tooth element.
The through-screw allows the prosthetic component to be attached to the implant by threading.
The prosthetic components are made of Titanium Gr. 5 ASTM F136 or in the case of UCLA also in Platinum Gold.

1.1 – Materials used
Patients are exposed to contact with the materials constituting the DM:

Titanio Gr. 5 ASTM F136

TABLE 1 Chemical Requirements

Element	Composition, %
Nitrogen, max	0.05
Carbon, max	0.08
Hydrogen, max	0.012[A]
Iron, max	0.25
Oxygen, max	0.13
Aluminum	5.5–6.50
Vanadium	3.5–4.5
Titanium[B]	balance

Platinum Gold
AU=60%; PT=24.9%; IR=0.1%; PD=15%

Its use is not recommended in patients with allergies or hypersensitivity to these materials

The device does not contain or incorporate:
- a medicinal product including a derivative of human blood or plasma
- human tissues or cells, or derivatives thereof, or
- tissues or cells of animal origin, or derivatives thereof, covered by Regulation (EU) No. 722/2012

2 - Warnings
Since DM is used in the application of implant procedures for functional and aesthetic rehabilitation resulting from the loss or congenital absence of one or more teeth, it should only be used by dentists with specialist training.
Any serious incidents occurring in connection with devices covered by the Instructions for Use must be reported to ISOMED as well as to the competent authority of the Member State in which the patient and/or user reside.
ISOMED devices have not been evaluated for compatibility and safety in magnetic resonance imaging (MRI) environments. The implants were not tested for heating, migration or the possibility of creating MRI image artefacts in magnetic resonance imaging (MRI) environments. The safety of ISOMED implants in the magnetic resonance imaging (MRI) environment is unknown. MRI scanning in a patient who has these devices may cause heating, migration or the possibility of creating artefacts in the MRI image.

3 - Precautions
Prosthetic Components must be cleaned and sterilised before their use in the patient.

4 - Restrictions on Use
Use only for its intended purpose.
Prosthetic components may only be coupled with devices specified by ISOMED in its catalogue. Combination with different devices may cause failure. It is recommended not to exceed a torque of 35Ncm when tightening the through-bolt for abutments and UCLA.
The device is disposable, reuse may compromise the safety features of the device making it unsuitable for its intended use. ISOMED explicitly declares DM disposable and assumes no liability for any re-use by users.

5 - Mode of use
When the mucous membrane has healed, replace the healing screw with the abutment/UCLA and secure it with the through-screw.
In the case of ball abutments, screw the abutment onto the implant after inserting the titanium collar. The coping is used by the dental technician for placement on the removable denture. Take the two rubber rings; one is used to prevent the resin from undercutting the ball while the other must be supplied to the dental technician to create a free circle around the four flexible wings of the coping.
Cleaning: can be conducted by soaking for 5 minutes in multi-enzymatic detergent followed by manual disinfection for about 2 minutes with an absorbent cloth soaked in alcohol-based disinfectant (70% alcohol).
Sterilization: Steam autoclave; 134° cycle for 4', 2 bar.
Further procedures other than those defined must be validated.

6 - Patient information and traceability
Current regulations require the patient to be informed by the doctor about the risks related to the device and possible surgical complications, as well as the need for periodic check-ups and in case of unexpected situations. For the purposes of implant traceability, the package contains two labels with the device's identification data; one must be affixed to the patient's medical record and the second to the 'Personal Card'.
The warnings, precautions or measures to be taken by the patient or a healthcare professional in relation to
Mutual interference with reasonably foreseeable external influences, medical examinations or environmental conditions as well as information on the expected life of the device and any necessary follow-up are given at www.isomed.it

The summary relating to safety and clinical performance (SSCP) in accordance with art. 32 of Regulation (EU) 745/2017, is available in the Customer area of the website www.isomed.it. In the European database of medical devices EUDAMED (https://ec.europa.eu/tools/eudamed) it is possible to view the summary relating to the safety and clinical performance of "dental implant" devices, whose Basic UDI-DI is:

Monconi, Monconi Angolati e relativa vite passante, connettori	**805957543PR0001F6**
Basette estetiche	**805957543PR0002F8**
Cannule per cementazione	**805957543PR0003FA**
UCLA	**805957543PR0004FC**
Monconi a palla, collarini ed emisfere	**805957543PR0005FE**

The physician and/or patient must report any serious incidents occurring with the device to the ISOMED manufacturer and to the competent authority of the Member State where the user and/or patient is established.

7 - Storage Precautions
Store in a dry place and do not expose to direct sources of heat or sunlight.

8 - Disposal
In the case of DM disposal needs, one can proceed by referring to local laws concerning special medical waste at risk of contamination. The DM must be cleaned and sterilised before disposal.

CE 0426	REF DM Code	Manufacturer	LOT Lot number	UDI UDI code	Date of manufacture	www.isomed.it	Disposable
MD Medical Device							