Prosthetic Manual
Single crown and bridges for B.O.P.T. technique
Prama Prosthetic Manual
Complete protocols for the realization of crowns and cemented bridges

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Guide chart to the single prosthetic connection

All measurements are given in mm, unless indicated otherwise.
Connection details

The connection is characterized by the Collex collar, documented by 16 years of clinical success, which has the function of stabilizing the prosthesis and guarantees the correct distribution of the masticatory loadings. In order to document and quantify the advantages of the Collex connection a FEM analysis has been performed, which compares this connection.


The connection takes up the whole emergent portion of the implant and it is clearly visible during the prosthetic manoeuvres. The platform is the same for all the implant diameters, simplifying in this way the management of the prosthetic components.
Important warning

The precision of this coupling is possible only thanks to a strict study of the working tolerances, so the benefits of the Contracone seal are obtained only when using original Sweden & Martina prosthetic components. Using non-original products not only invalidates the concept of the Contracone, but it risks creating large gaps at the connection level.

**Contracone seal**

One of the key factors in determining the success of an implant-prosthetic rehabilitation is the absence of infiltration of bacteria; to achieve this aim there must be no spaces between the platform of the implant and that of the abutment, where bacteria could penetrate and migrate towards the implant well, giving rise to anaerobic proliferations that may be dangerous for the peri-implant tissues. Sweden & Martina have patented a particular micromechanical processing which tapers both the surfaces that rest on each other: in this way a mechanical barrier is created, which guarantees a peripheral seal that is able to limit the access of bacteria and to preserve the peri-implant tissues against possible inflammations.

**The comparative study:**

*Microbiological assessment of the implant-abutment interface in different connections: cross-sectional study after 5 years of functional loading.*

Canullo L., Penarrocha- Oltra D., Soldini C., Mazzocco F., Penarrocha M., Covani U.


has proved that the Contracone technology, applied to the internal hexagon connection, has the same capability to limit the bacterial infiltrate of a standard conical connection.

**Prosthetic screw with Full Head technology**

The prosthetic screw of the Prama posts have been specially studied in order to allow a wide freedom of angled posts personalization. As a matter of fact the head of the screw is full and presents an external hexagon of reduced dimensions compared to one standard prosthetic screw with internal hexagon. The head of the screw presents a conical support which improves the prosthetic tightening without impeding its possible removal. For the screwing and unscrewing manoeuvres of this particular prosthetic screw, dedicated screwdrivers are available, in steel for surgical use, in three different lengths with dynamometric ratchet graft and one screwdriver with right angle shank.
Prama neck

The transgingival Prama neck is characterized by a cylindrical part of 0.80 mm and by a hyperbolic portion 2.00 mm high created in order to guarantee an effective continuity with the post. This absence of sharp edges will allow the mucosa to slide on titanium without finding obstacles and to reach the adaptation profile established by the prosthodontist. Moreover, it will facilitate the positioning of the closure of the crown in any part of the transgingival section. The hyperbolic profile has different width in the three implant diameters, in this way the connection diameter is always 3.40 mm.

The characteristic machined surface of the transgingival section has the double advantage to facilitate the adherence of the soft tissues, helping the development of a gingival seal with a high content of collagen fibres, therefore very steady.

ZirTi Gold Machined:
In the implants with ZirTi surface, the transgingival section of the implant is submitted to a controlled passivation process which gives a golden yellow colour to the metal, highly mimetic, both under the soft tissues and under the translucent materials used in the implantoprosthesis.
The Prama surgical kit

The Prama surgical kit contains all the surgical and prosthetic instruments useful for the management of all the operating phases, from the insertion of the implant to the definitive prosthesis.

Key

1 Prama screwdrivers
2 Screwdriver with the connector for dynamometric ratchet
3 Hand screwdrivers
4 Dynamometric ratchet CRI5
5 Hand screwdriver for instruments with right angle shank and with hexagonal connection to be used with the ratchet
6 BPM-15 extension

For the details related to the surgical instruments, please refer to Prama catalogue and surgical manual. In this prosthetic manual we concentrate the information related only to the instruments dedicated to the prosthetic phase.
Screwdrivers for prosthetic screws

All the screwdrivers are made of stainless steel for surgical use. There are two kinds of drivers for the Prama implants: the traditional ones (on the left in the picture) and the ones for the screws with Full Head technology (on the right). They differ in the design of the tip, studied in the first case to join a screw with internal hexagonal connection and in the other with external hexagonal connection, therefore they are not interchangeable. In both cases the slightly conical coupling between the driver and the screw allows an appropriate retention when carrying the screw into the oral cavity. Both drivers families are available in different shank lengths, depending on the patient anatomy. The standard screwdrivers are available also in the digital one-piece version, this means that they are integral with the hand knob which allows the grip.

**Important warning**

Excessive torques can damage the thread of the well or of the sharp edges of the connecting screws and damage the thread of the drivers, causing also severe intra-surgical and prosthetic complications. The recommended torque for the tightening of the different components are summarized in the following chart.

<table>
<thead>
<tr>
<th>description</th>
<th>recommended torque</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connecting screws, healing abutments</td>
<td>(Manually) 8-10 Ncm</td>
</tr>
<tr>
<td>All prosthetic screws</td>
<td>20-25 Ncm</td>
</tr>
<tr>
<td>Transfer screws</td>
<td>(Manually) 8-10 Ncm</td>
</tr>
</tbody>
</table>

Given the importance of the tightening torque, it is recommended to use always the screwdrivers with hexagonal connection, keeping always the exerted torque under control with the dynamometric ratchet. To facilitate the joint of the screws or of the threaded sections of the prosthetic components, the screwing should be started with the digital screwdrivers.
**Prama screwdrivers**

The specific screwdrivers for the screws with Full Head technology are available in the version with hexagonal connection for dynamometric ratchet, with different shank lengths. A screwdriver with right angle connector is also available. The instruments tip has an hexagonal notch, which connects the full hexagon of the Full Head screws, giving the retention needed for the carriage of the screw. These screwdrivers cannot be used for the connecting screws of the temporary posts or for other types of screws in the catalogue.

<table>
<thead>
<tr>
<th>code</th>
<th>description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L-HSM-EX</td>
<td>Screwdriver for screw with Full Head technology, digital, extra short</td>
</tr>
<tr>
<td>L-HSML-EX</td>
<td>Screwdriver for screw with Full Head technology, digital, short</td>
</tr>
<tr>
<td>L-HSMXL-EX</td>
<td>Screwdriver for screw with Full Head technology, digital, long</td>
</tr>
<tr>
<td>L-HSM-CA</td>
<td>Screwdriver for screw with Full Head technology, for right angle</td>
</tr>
</tbody>
</table>

**Screwdriver for right angle**

The surgical kit contains also a screwdriver with right angle shank, very practical both in the surgical and prosthetic phase if it is used with a micromotor with the torque control. This screwdriver can be used only for the tightening of the posts whose hole for the passing of the screw is not longer than 11.00 mm.

<table>
<thead>
<tr>
<th>code</th>
<th>description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSM-20-CA</td>
<td>Screwdriver for connecting screws, with right angle shank</td>
</tr>
</tbody>
</table>
Digital screwdrivers

Their design makes them very practical in the surgical phases of uncovering and management of the healing abutments. They must not be used in the final prosthetic phases because they do not allow the torque control. Some of these drivers are also contained in the surgical kits of the Premium, Kohno and Shelta systems. Please refer to the catalogues and the surgical manuals of the individual systems for details.

<table>
<thead>
<tr>
<th>code</th>
<th>description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSMXS-20-DG</td>
<td>Screwrivers for surgical cover screws and connecting screws, digital, extra short</td>
</tr>
<tr>
<td>HSM-20-DG</td>
<td>Screwrivers for surgical cover screws and connecting screws, digital, short</td>
</tr>
<tr>
<td>HSML-20-DG</td>
<td>Screwrivers for surgical cover screws and connecting screws, digital, long</td>
</tr>
</tbody>
</table>

All measurements are given in mm, unless indicated otherwise.
Screwdrivers for use with the dynamometric ratchet

The drivers with a hexagonal connector at the top are designed for use with the dynamometric ratchet with the function of controlling torque. Please refer to the catalogue and the surgical manual for details.

<table>
<thead>
<tr>
<th>code</th>
<th>description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSM-20-EX</td>
<td>Screwdriver for connecting screws, with hexagonal connector for dynamometric key or hand knob, short</td>
</tr>
<tr>
<td>HSML-20-EX</td>
<td>Screwdriver for connecting screws, with hexagonal connector for dynamometric key or hand knob, long</td>
</tr>
</tbody>
</table>

**Important warning**

All the screwdrivers for dynamometric ratchet have a red polymer O-ring in the connecting hexagon that guarantees friction between the instruments and therefore a correct grip of the components. This O-ring must be checked periodically and replaced when worn or when no longer able to exert the correct friction.

A kit of 5 spare O-rings is available, it can be purchased with the code ORING180-088.

<table>
<thead>
<tr>
<th>code</th>
<th>description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPM-15</td>
<td>Extension for bone taps, mounters, drivers and manual drivers, with hexagonal connector for dynamometric key</td>
</tr>
</tbody>
</table>
Dynamometric ratchet CRI5

A special ratchet (code CRI5-KIT) is available, with its own adjustment key, for quickly screwing the torque adjustment ring nut, and with gel lubricant for maintenance. The ratchet may be used with torque adjustment from 10 to 70 Ncm or in a blocked position without torque control. When using as a prosthetic ratchet for fastening the screws, refer to the torque values given in the table on page 9. The ratchet key CRI5 is a reusable instrument that can be disassembled, and is sold unsterile. It is contained in all surgical kits for implant systems. It can also be supplied separately.

Before each use, this instrument must be cleaned and sterilised according to the instructions on page 52. Adequate maintenance, performed following in detail all the step by step instructions for the disassembly and correct reassembly of the device during cleaning operations, is essential for the correct functioning of the device and for its durability. Personnel who use this tool must be suitably trained, and they must have read the instructions in this manual, or in the surgical manuals of the various implant systems, prior to handling the device. After sterilisation, the key is ready for use. A test to verify the correct assembly and functioning of the key is necessary before any surgical or prosthetic interventions.
After sterilisation, the key is ready for use. A test to verify the correct assembly and functioning of the key is necessary before any surgical or prosthetic interventions. The torque is adjusted by aligning the marking of the desired torque in the circular opening of the handle. The "IN" arrow legible on the top of the head indicates the screwing position of the key. The "OUT" arrow legible on the top of the head indicates the loosening or unscrewing position. An unlimited torque position is obtained by positioning the torque adjustment device up to the line marked "R" on the handle of the ratchet body.
**Important warning**

The torque is adjusted by screwing/unscrewing the ring nut located at the bottom of the instrument’s handle. The torque must always be adjusted on the rise, starting screwing from a lower value until the desired torque is reached, or unscrewing the ring nut in a clockwise direction.

To do this, if it is necessary to set a torque lower than the last one used, you must unscrew the ring nut by two turns below the value of the desired new torque, and work up to that value by rescrewing the ring nut in a clockwise direction.

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*In order to set a torque value, turn the ring nut in a clockwise direction until the wanted value.*

*To turn down a torque value of work of the ratchet, first it is necessary to unscrew the ring nut in an anticlockwise direction until reaching a value inferior of the wanted one, then proceed with the clockwise direction screwing until the chosen torque.*

The ring nut may be screwed and unscrewed by hand, but to speed up these operations the kit also contains a driver that allows it to be turned quickly.

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Any deterioration of the screwing, insertion and torque mechanisms must be checked by personnel responsible for the use and maintenance of this dental instrument. The pieces of this mechanism are not interchangeable; one piece from one key cannot be replaced by a piece from another key as each ratchet is calibrated INDIVIDUALLY. If a piece is lost, please return the instrument to Sweden & Martina for repair. No components for assembling the ratchet can be sold individually.

Failure to follow the instructions provided may cause problems of unscrewing and stability of the prosthesis.
Techniques for taking the impression

In implant-prosthetic procedures, the phase of taking the impression is fundamental for the success of any treatment plan, since the transmission to the laboratory of information as error-free as possible allows a reduction of work times and above all the creation of products free from stress which do not transmit undesired stress to the implants. The impression can be taken at different surgical moments, depending on the protocols and/or on practice habits.

On all the Prama implants it is possible to take the impression on the implants using the open tray technique with Pick-up transfers. For distal zones in which the manoeuvres of screwing and unscrewing of the screw are difficult, and also in cases of scarce oral opening, it is possible to use the Pull-Up transfers in radiopaque PEEK together with the Pick-up transfers. The retentive tabs ensure a precise detection of the implant platform and at the same time make easier the extraction of the transfer from the oral cavity.

The components for the impression and the creation of the model are produced with the same machines that make the implants; this ensures a real guarantee of precision from the point of view of tolerance and fidelity in the reproduction of the clinical situation. The analogues are characterized by anodic coating according to the colour code to facilitate recognition of the implant diameter and laboratory phases.

Important warning

In all cases it is recommended to use new transfers and analogs, so as to ensure maximum coupling precision at the connection level. Transfers and analogs that have been used several times reciprocally deform the walls of their respective hexagons, transferring an error to the impression which, especially in the case of multiple structures, may lead to stress in the prosthesis which is transferred to the implants, undermining the good clinical result.
<table>
<thead>
<tr>
<th>Ø implant</th>
<th>Ø 3.80 mm</th>
<th>Ø 4.25 mm</th>
<th>Ø 5.00 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pick-up transfer, straight emergence Connecting screw included</td>
<td>L-TRA-380</td>
<td>L-TRA-425</td>
<td>L-TRA-500</td>
</tr>
<tr>
<td></td>
<td>Ø 3.30...</td>
<td>Ø 3.30...</td>
<td>Ø 3.30...</td>
</tr>
<tr>
<td></td>
<td>9.00</td>
<td>9.00</td>
<td>9.00</td>
</tr>
<tr>
<td>Connecting screw for Pick-up transfer complete with the transfers and may be ordered also separately as a spare Single Pack</td>
<td>VTRA2-180-15</td>
<td>VTRA2-180-15</td>
<td>VTRA2-180-15</td>
</tr>
<tr>
<td></td>
<td>M 1.80...</td>
<td>M 1.80...</td>
<td>M 1.80...</td>
</tr>
<tr>
<td></td>
<td>15.00</td>
<td>15.00</td>
<td>15.00</td>
</tr>
<tr>
<td>Pull-up transfer straight emergence</td>
<td>A-TRAP-330</td>
<td>A-TRAP-330</td>
<td>A-TRAP-330</td>
</tr>
<tr>
<td></td>
<td>Ø 3.30...</td>
<td>Ø 3.30...</td>
<td>Ø 3.30...</td>
</tr>
<tr>
<td></td>
<td>11.50</td>
<td>11.50</td>
<td>11.50</td>
</tr>
<tr>
<td>Laboratory analogue</td>
<td>L-ANA-380</td>
<td>L-ANA-425</td>
<td>L-ANA-500</td>
</tr>
<tr>
<td></td>
<td>Ø 3.80...</td>
<td>Ø 4.25...</td>
<td>Ø 5.00...</td>
</tr>
<tr>
<td></td>
<td>12.00</td>
<td>12.00</td>
<td>12.00</td>
</tr>
</tbody>
</table>

Recommended torque for transfer screw: 8-10 Ncm manual.

See titanium Gr. 5 technical characteristics on page 43.
See PEEK technical characteristics on page 44.

All measurements are given in mm, unless indicated otherwise.
Impression taking on single implant

The Prama implant presents a transgingival emergence, for this reason it is dedicated to techniques with only one surgical phase. If the impression is taken after an healing period, remove the surgical connecting screws or the healing abutments.

Fix the pick-up transfer with the dedicated screw supplied and the series HSM** driver of the most suitable length, without going beyond the 8-10 Ncm torque.

Please note: the driver for the surgical cover and connecting screws in digital version is available in different shank lengths depending on the clinical requirements. It is also available the version with hexagonal connection for dynamometric ratchet with right angle shank. See the chart on page 11 for the technical details of the abovementioned drivers.

Make sure that the personalized tray, positioned in the mouth, contains all the height of the transfer in its inside and that the transfer screw top comes out for an appropriate and sufficient section of the dedicated hole on the emergent section of the implant. Inject the precision impression material (SKY IMPLANT LIGHT, cod SKY14) only around the transfers and the emergent section of the implants.
Fill the impression tray with a consistent material (SKY IMPLANT ONEMIX-ED, cod. SKY08) in all the arch. Place the tray in situ and wait the hardening times following the instructions.

Unscrew the transfer screw and remove it from the impression in order to avoid that at the moment of the impression tray removal they can accidentally fall in the mouth of the patient. Remove the tray: The Pick up transfer stays enclosed in the impression.

Screw the implant analog (L-ANA*) to the transfer through a transfer screw, repositioned in the hole left by it in the impression material. The recommended torque is 8-10 Ncm. Drain the model as usual.
**Impression on bridge**

The Prama implant presents a transgingival emergence, for this reason it is dedicated to techniques with only one surgical phase. If the impression is taken after an healing period, remove the surgical connecting screws or the healing abutments.

Fix the pick-up transfer with the dedicated screw supplied and the series HSM** driver of the most suitable length, without going beyond the 8-10 Ncm torque. If needed, splint the transfers with thread and resin, waiting the polymerization times indicated by the manufacturer. **Please note:** the driver for the surgical cover and connecting screws in digital version is available in different shank lengths depending on the clinical requirements. It is also available the version with hexagonal connection for dynamometric ratchet with right angle shank. See the chart on page 11 for the technical details of the abovementioned drivers.

Make sure that the personalized tray, positioned in the mouth, contains all the height of the transfer in its inside and that the transfer screw top comes out for an appropriate and sufficient section of the dedicated hole on the emergent section of the implant. Inject the precision impression material (SKY IMPLANT LIGHT, cod SKY14) only around the transfers and the emergent section of the implants.
Fill the impression tray with a consistent material (SKY IMPLANT ONEMIX-ED, cod. SKY08) in all the arch. Place the tray *in situ* and wait the hardening times following the instructions.

Unscrew the transfer screw and remove it from the impression in order to avoid that at the moment of the impression tray removal they can accidentally fall in the mouth of the patient. Remove the tray: the Pick-up transfer stays enclosed in the impression.

Screw the implant analog (L-ANA-*) to the transfer through a transfer screw, repositioned in the hole left by it in the impression material. The recommended torque is 8–10 Ncm. Drain the model as usual.
Impression on bridge with mixed technique

The Prama implant presents a transgingival emergence, for this reason it is dedicated to techniques with only one surgical phase. If the impression is taken after an healing period, remove the surgical connecting screws or the healing abutments.

To facilitate the impression phase in the distal sectors and in patients with scarce oral opening, it is possible to use the Pull-up transfers together with the Pick-up transfers. The Pull-up transfers exercise retention in the connection with the dedicated retentive tabs, while the Pick-up transfers have to be fixed to the implant with the dedicated transfer screw supplied with a maximum torque of 8-10 Ncm. In order to do this operation use the dedicated driver of the series HSM** of the most suitable length. See the list of all the available instruments on page 11.

Make sure that the personalized tray, positioned in the mouth, contains all the height of the transfer in its inside and that the transfer screw top comes out for an appropriate and sufficient section of the dedicated hole on the tray.
If the Pull-up transfer proves to be too long it is possible to shorten it congruently with the space available cutting one or two retentive models with a cutting disk.

Reposition the modified Pull-up transfer on the implant exerting a light manual pressure.

Inject a precision impression material (SKY IMPLANT LIGHT, cod SKY14) only around the transfers and the emergent section of the implants.
Fill the impression tray with a consistent material (SKY IMPLANT ONEMIX-ED, cod. SKY08) in all the arch. Place the tray *in situ* and wait the hardening times following the instructions.

Unscrew the transfer screw and remove it from the impression in order to avoid that at the moment of the impression tray removal they can accidentally fall in the mouth of the patient.

Remove the tray; both the Pick-up transfer and the Pull-up transfers are enclosed in the impression.
Important warning
The Pull-up transfers are not characterized by color codes, for this reason it is necessary that the physician gives to the laboratory clear indications on the implant diameter corresponding to each single position, so that the laboratory can insert the correct analog in the model. It would be advisable that the physician sends the analogs already fixed to the related transfers to the laboratory, in order to facilitate the correct realization of the model. Drain the model as usual.

Combine each transfer with the corresponding implant analog (L-ANA-*+) screwing the Pick-up transfers through the transfer screw, repositioned in the hole left by it in the impression material. The recommended torque is 8-10 Ncm. For the Pull-up transfers a pressure of the analog in the position will be sufficient.
Healing phase and conditioning

The Prama implants present a transgingival neck which makes them suitable for protocols with only one surgical phase, during the healing phase in the presence of a biotype it can often be useful to condition the soft tissues with a straight healing abutment, available in different heights. In this way a gingival tunnel is created, which will avoid to the patient the pain at the moment of the prosthesis insertion.

The Prama systematics proposes, moreover, a series of posts for B.O.P.T. temporaries screwed in Reef resin, whose particular nanostoichiometric conformation allows a high capability resistance to the bacterial attack which lasts in the time and makes more difficult the plaque adherence, facilitating the healing phase. Moreover, the Reef resin presents a great chair-side use easiness allowing an easy construction of the restauration morphology which will allow an optimal adaptation of the soft tissues on the shapes. The posts are available both with repositioning hexagon, for single implants, and without repositioning hexagon, for bridges and full arch.
<table>
<thead>
<tr>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
</table>
| Healing abutment  
Straight emergence profile  
Transgingival H. 2.00 mm | A-TMG-330-2 |
| Healing abutment  
Straight emergence profile  
Transgingival H. 3.00 mm | A-TMG-330-3 |
| Healing abutment  
Straight emergence profile  
Transgingival H. 5.00 mm | A-TMG-330-5 |
| B.O.P.T. repositionable temporary  
Reef resin posts  
Connecting screw included | A-PPF-330-EX |
| B.O.P.T. non repositionable temporary  
Reef resin posts  
Connecting screw included | A-PPF-330 |
| Single pack  
Pack of 10 pieces  
Connecting screw for resin B.O.P.T. posts supplied with the temporary posts, it can also be ordered separately as a spare | VM2-180  
VM2-180-10 |

Recommended torque: 8-10 Ncm.

See titanium Gr. 5 technical characteristics on page 43.
See Reef resin technical characteristics on page 45.

All measurements are given in mm, unless indicated otherwise.
Healing phase and conditioning: single crowns

If you do not opt for an immediate load protocol, remove the surgical cover screw or the healing abutment.

Fix the implant to the Reef resin B.O.P.T. temporary post with repositioning hexagon, using the HSM* series driver of the most suitable length. See the range of available drivers on page 11. Initially leave the temporary post of its original length.

Insert on the B.O.P.T. temporary post a ready-made moulded prostheses realized in the laboratory and pierced to create a space suitable for the slipping on the resin cylindrical body.
Fix the temporary crown to the temporary B.O.P.T. post with some resin in the occlusal margin. Waiting the polymerization according to the times and ways indicated by the manufacturer.

Once the polymerization has taken place, remove the two parts, now jointed, reposition them on an implant analog and proceed with the resin filling of the whole left internal space between the ready-made moulded prostheses and the B.O.P.T. temporary post.

Finish off the screwed temporary post both in the occlusal section, removing the post excess, and in the apical section, according to the emergence profiles adapting shapes.
Screw the temporary post to the implant with the dedicated screw and a HSM* series driver (see chart on page 11)

**Important warning**
It is recommended not to go beyond the 8-10 Nm tightening torque.

The temporary tooth will contribute not only to the adequate quality of the life of the patient, but also to the correct conformation of the gingival tissues which will receive the definitive prosthesis with optimal aesthetic results.
Healing phase and conditioning: single crowns

If you do not opt for an immediate load protocol, remove the surgical cover screw or the healing abutment.

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Finish off the screwed temporary post both in the occlusal section, removing the post excess, and in the apical section, according to the emergence profiles adapting shapes.
Screw the temporary post to the implant with the dedicated screw and a HSM* series driver (see chart on page 11).

**Important warning**
It is recommended not to go beyond the 8-10 Nm tightening torque.

The temporary tooth will contribute not only to the adequate quality of the life of the patient, but also to the correct conformation of the gingival tissues which will receive the definitive prosthesis with optimal aesthetic results.
Realization of cemented definitive rehabilitation: straight and angled posts

The pre-maid straight and angled posts are manufactured in Gr. 5 titanium and subsequently submitted to a controlled passivation process which implies the dye-toning of their superficial color: the result is a characteristic gold straw-yellow. This color is obtained through an oxidation process and for this reason without any kind of coating, so it guarantees the use of a highly biocompatible surface and with high aesthetic value.

The tightening of the posts is done with a dedicated screw with Full Head technology with conical support and full connection, so that it guarantees higher possibilities of personalization in case of particular angles with respect to a traditional connecting screw, whose head would have a definitively higher encumbrance.

Since the Prama implants have the same connection platform for all the diameters, the straight and angled posts are available in only one prosthetic measurement.
Important warning
It is recommended always to use test screws for the laboratory phases and to keep the new screw supplied for the final fastening in the mouth.

<table>
<thead>
<tr>
<th>description</th>
<th>code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straight post for Prama implant connecting screw included</td>
<td>L-MD-340</td>
</tr>
<tr>
<td>Angled post for Prama implant connecting screw included</td>
<td>L-MA15-340</td>
</tr>
<tr>
<td>Single pack</td>
<td>L-VM-180</td>
</tr>
<tr>
<td>Pack of 10 pieces</td>
<td>L-VM-180-10</td>
</tr>
<tr>
<td>Spare connecting screw</td>
<td></td>
</tr>
</tbody>
</table>

Recommended tightening torque: 20-25 Ncm

See technical characteristics of the Gr. 5 titanium on page 43

All measurements are given in mm, unless indicated otherwise.
USE PROTOCOLS

**Cemented single crowns**

Screw the Prama transfer to the analog with the dedicated HSM* series driver.

With wax or resin prepare a box for the impression and drain the model as usual; the Prama analog will reproduce exactly the position of the implant transgingival neck.

Screw the straight or angled post to the analog, depending on the prosthetic requirements, using a Full Head technology screw with conical support and the dedicated driver of the L-HSM* series: see the available range on page 10.

**Important warning**

It is recommended always to use test screws for the laboratory phases and to keep the new screw supplied for the final fastening in the mouth. The tightening torque on the model has not to go beyond 8-10 Ncm.
Once the models are mounted in the articulator, define the heights of the post in relation with the space with the antagonist. At the same time define the wanted morphology of the soft tissues modelling the gypsum and recreating a new emergence profile with the dedicated silicone for the gum simulation.

Define the shape, volume and occlusion implementing a diagnostic wax-up and realizing the crown following the wished method.

Screw the post to the implant, using a Full Head technology new screw with conical support and the dedicated driver of the L-HSM series: see the available range on page 10.

**Important warning**

The recommended tightening torque is: 20-25 Ncm.
Cement the crown on the post.

The gums will adapt on the morphology of the crown recreating the emergence profiles previously planned.
Cemented bridge

Screw the Prama transfer to the analog with the dedicated HSM* series screwdrivers. See the range of available screwdrivers on page 11.

**Important warning**
Always refer to the color code in order to match correctly the transfers and the analogs of the correct diameters.

With wax or resin prepare a box for the impression and drain the model as usual; the Prama analog will reproduce exactly the position of the implants transgingival neck.

Screw the straight or angled posts to the analogs, depending on the prosthetic requirements, using a Full Head technology screw with conical support and the dedicated driver of the L-HSM* series: see the available range on page 10.

**Important warning**
It is recommended always to use test screws for the laboratory phases and to keep the new screw supplied for the final fastening in the mouth. The tightening torque on the model has not to go beyond 8-10 Ncm.
Once the models are mounted in the articulator, define the heights of the posts in relation with the space with the antagonists. At the same time define the wanted morphology of the soft tissues discarding the gypsum and recreating a new emergence profile with the dedicated silicone for the gum simulation.

Define the shapes, volumes and occlusions implementing a diagnostic wax-up and realizing a bridge following the wished method.

Screw the posts to the implant, using Full Head technology new screws with conical support and the dedicated driver of the L-HSM* series: see the available range on page 10.

**Important warning**
The recommended tightening torque is: 20-25 Ncm.
Cement the bridge on the posts.

The gums will adapt on the shapes outlined by the bridge recreating the emergence profiles previously planned.
### Composition of the materials

**Gr. 4 titanium (cold worked)**

<table>
<thead>
<tr>
<th>Chemical Composition</th>
<th>Maximum Allowed Values (%)</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrogen</td>
<td>0.05</td>
<td>+/- 0.02</td>
</tr>
<tr>
<td>Carbon</td>
<td>0.08</td>
<td>+/- 0.02</td>
</tr>
<tr>
<td>Hydrogen</td>
<td>0.015</td>
<td>+/- 0.002</td>
</tr>
<tr>
<td>Iron</td>
<td>0.50</td>
<td>+/- 0.10 (≤0.25)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+/- 0.15 (&gt;0.25)</td>
</tr>
<tr>
<td>Oxygen</td>
<td>0.40</td>
<td>+/- 0.02 (≤0.20)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+/- 0.03 (&gt;0.20)</td>
</tr>
<tr>
<td>Titanium</td>
<td>Remainder</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mechanical Properties</th>
<th>Minimum Allowed Values (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile Stress</td>
<td>680 MPa (N/mm²)</td>
</tr>
<tr>
<td>Yield Strength (0.2%)</td>
<td>520 MPa (N/mm²)</td>
</tr>
<tr>
<td>Ultimate Elongation</td>
<td>15 %</td>
</tr>
<tr>
<td>Section Reduction</td>
<td>25 %</td>
</tr>
</tbody>
</table>

* This technical information complies with the express specifications of the regulations in force for the use of Gr. 4 titanium in implantology.

**Please note:** the use of bars obtained from cold processing, for the production of Sweden & Martina Spa implants, allows the exploitation of the mechanical characteristics of tensile strength and yield strength about 15% higher than those that can be obtained with a hot process (respectively 550 MPa and 483 MPa).
**Gr. 5 titanium**

<table>
<thead>
<tr>
<th>Chemical composition</th>
<th>Maximum allowed values (%)</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrogen</td>
<td>0.05</td>
<td>+/- 0.02</td>
</tr>
<tr>
<td>Carbon</td>
<td>0.08</td>
<td>+/- 0.02</td>
</tr>
<tr>
<td>Hydrogen</td>
<td>0.012</td>
<td>+/- 0.002</td>
</tr>
<tr>
<td>Iron</td>
<td>0.25</td>
<td>+/- 0.10</td>
</tr>
<tr>
<td>Oxygen</td>
<td>0.13</td>
<td>+/- 0.02</td>
</tr>
<tr>
<td>Aluminium</td>
<td>5.50÷6.50</td>
<td>+/- 0.40</td>
</tr>
<tr>
<td>Vanadium</td>
<td>3.50÷4.50</td>
<td>+/- 0.15</td>
</tr>
<tr>
<td>Titanium</td>
<td>Reminder</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mechanical properties</th>
<th>Minimum allowed values (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tensile stress (for bar diameters up to 44.45 mm)</td>
<td>860 MPa (N/mm²)</td>
</tr>
<tr>
<td>Yield strength (0.2%)</td>
<td>795 MPa (N/mm²)</td>
</tr>
<tr>
<td>Ultimate elongation</td>
<td>10 %</td>
</tr>
<tr>
<td>Section reduction</td>
<td>25 %</td>
</tr>
</tbody>
</table>

**This technical information complies with the express specifications of the regulations in force for the use of Gr. 5 titanium in implantology.**
### PEEK

<table>
<thead>
<tr>
<th>Chemical Designation</th>
<th>Radiopaque</th>
<th>Classic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyetheretherketone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polyetheretherketone</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Colour</th>
<th>Radiopaque</th>
<th>Classic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cream white opaque</td>
<td></td>
<td>Cream white opaque</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physical and Mechanical Properties</th>
<th>Radiopaque</th>
<th>Classic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Density (g/cm³)</td>
<td>1.65</td>
<td>1.4</td>
</tr>
<tr>
<td>Modulus of Elasticity (tensile test DIN EN ISO 527-2) (MPa)</td>
<td>5200</td>
<td>4100</td>
</tr>
<tr>
<td>Tensile Strength (DIN EN ISO 527-2) (MPa)</td>
<td>77</td>
<td>97</td>
</tr>
<tr>
<td>Tensile Strength at Yield (DIN EN ISO 527-2) (MPa)</td>
<td>77</td>
<td>97</td>
</tr>
<tr>
<td>Elongation at Yield (DIN EN ISO 527-2) (%)</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Elongation at Break (DIN EN ISO 527-2) (%)</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>Flexural Strength (DIN EN ISO 178) (MPa)</td>
<td>178</td>
<td>174</td>
</tr>
<tr>
<td>Modulus of Elasticity (flexural test) (DIN EN ISO 178) (MPa)</td>
<td>5000</td>
<td>4000</td>
</tr>
<tr>
<td>Compression Modulus (EN ISO 604) (MPa)</td>
<td>4000</td>
<td>3500</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Thermal Properties</th>
<th>Radiopaque</th>
<th>Classic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glass Transition Temperature (DIN 53765) (°C)</td>
<td>-</td>
<td>150</td>
</tr>
<tr>
<td>Service Temperature Short Term (°C)</td>
<td>300</td>
<td>300</td>
</tr>
<tr>
<td>Service Temperature Long Term (°C)</td>
<td>260</td>
<td>260</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Properties</th>
<th>Radiopaque</th>
<th>Classic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Absorption 24h / 96h (23°C) (DIN EN ISO 62) (%)</td>
<td>-</td>
<td>0.02/0.03</td>
</tr>
</tbody>
</table>
Reef resin

<table>
<thead>
<tr>
<th>Reef resin</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>description</td>
<td>acrylic material resistant to the bacterial colonization</td>
</tr>
<tr>
<td>Colour</td>
<td>translucent white</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>physical and mechanical properties</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>hardness (ASTM D92/ISO 6507)</td>
<td>17.5 +/- 0.5 Vickers</td>
</tr>
<tr>
<td>tensile strength</td>
<td>28.3 +/- 3.8 Mpa</td>
</tr>
<tr>
<td>compressive strength (ASTM D3410)</td>
<td>404.2 +/- 22 Mpa</td>
</tr>
<tr>
<td>bending strength (ASTM D790M)</td>
<td>67.5 +/- 15.3 Mpa</td>
</tr>
</tbody>
</table>
Clinical indications

Modern oral implantoprostesis, with immediate or deferred loading, is a well-tested and reliable discipline able to solve almost all edentulism problems, both functional and cosmetic. Restorations can replace a single tooth (implant-supported crown), a group of neighbouring teeth (implant-supported bridge) or an entire arch.

This manual refers to the realization of cemented prosthesis for the rehabilitation of single or multiple edentulism in the field of the B.O.P.T. technique.

Implant-prosthetic rehabilitation must meet certain fundamental criteria:
• the presence of a certain amount of bone;
• the primary stability of the implants after insertion;
• good periodontal (gingival) support;
• no bruxism (teeth grinding) or serious malocclusion;
• the presence of good occlusal balance (correct masticatory occlusal plane).

Warnings and contraindications

When assessing the patient, in addition to his/her eligibility as regards implant-prosthetic rehabilitation, it is usually necessary to consider the contraindications that apply to oral surgery procedures in general. These include:
• clotting disorders, anticoagulant therapy;
• healing or bone regeneration disorders;
• decompensated diabetes mellitus;
• metabolic or systemic diseases that compromise tissue regeneration with a particular influence on healing and bone regeneration;
• alcohol abuse, smoking and use of drugs;
• immunosuppressive therapy, such as: chemotherapy and radiotherapy;
• infections and inflammations, such as periodontitis and gingivitis;
• poor oral hygiene;
• inadequate motivation;
• occlusion and/or articulation disorders as well as an inadequate interocclusal space;
• inadequate alveolar process.

It is contraindicated to fit implants and implant restorations in patients with poor general or oral health, those who are unable to monitor their general conditions properly or those who have had organ transplants. Psychologically unstable patients, alcohol or drug abusers, and poorly motivated or uncooperative patients should also be considered unsuitable for this kind of treatment. Patients with poor periodontal health should first be treated and allowed to recover. In the presence of a lack of bone substance or poor quality of the receiving bone, such as to compromise the stability of the implant, suitable guided tissue regeneration must be performed prior to implant treatment. Contraindications also include: bruxism, allergy to titanium (extremely rare), acute or chronic infectious diseases, sub-acute chronic maxillary osteitis, systemic diseases, endocrine disorders, diseases resulting in microvascular disorders, pregnancy, breastfeeding, previous exposure to radiation, haemophilia, neutropenia, steroid use, diabetes mellitus, kidney failure and fibrous dysplasia. The normal contraindications common to all oral surgery must also be observed. Surgery is not recommended for patients on anti-coagulant, anticonvulsant and immunosuppressant therapies, with active inflammatory-infective processes of the oral cavity, and patients with BUN and creatinine values outside the norm. Patients with cardiovascular disease, hypertension, thyroid or parathyroid diseases, malignant tumours found in the 5 years preceding the operation, or nodular swellings must also be rejected. Chemotherapies reduce or eliminate the ability of osseointegration, therefore patients undergoing these treatments must be carefully screened before being rehabilitated with oral implantoprostheses. Numerous cases of bisphosphonate-associated perimplant osteonecrosis of the mandible have been reported in the literature. This problem particularly applies to patients treated intravenously.

Restoration work must always be planned in advance. Restoration planning must be performed in concert with the dental technician. The restoration-guided placement of implants facilitates the prosthodontist’s work and provides better guarantees in terms of duration. It is recommended to
collect and file all the clinical, radiological and radiographic records. Each pack reports the code, description of the contents and batch number. These same details are also indicated on the labels to be attached to the patient’s records and must be referred to by the doctor whenever necessary. When handling the devices, both during use and during cleaning and sterilization, it is recommended to use surgical gloves for personal protection from bacterial contaminations. Failure to comply with these warnings may lead to cross infection. The packaging conforms to European standards.

Regulatory information

The planning and the production of the devices subject of this use manual is performed in conformity with the most up-to-date harmonized directive and norms regarding the used materials, the production processes, the sterilization, the supplied information, the packaging.

On each package the code, the description of the content and the batch number are reported. These data, which are reported also on the labels in the packages, have to be mentioned by the physician for any communication regarding them.

The prosthetic components and the instruments manufactured by Sweden & Martina do not contain neither materials of human or animal origin, nor phthalates. It is recommended to verify with the patients possible allergies to the materials used.

The titanium allergy is a very rare phenomenon, but not impossible. For this reason it is recommended to verify previously with the patients that they are not allergic to this material. See pages 42-45 for the detailed technical sheets of all the materials used, for the verification of the related chemical compositions and for the mechanical-physical characteristics.

Identification of the manufacturer

The manufacturer of the prosthetic components and of the instruments described in this manual is:

Sweden & Martina
Via Veneto 10
35020 Due Carrare (Padova) – Italia
Tel. +39 049.9124300 - Fax + 39 049.9124290
e-mail: info@sweden-martina.com
www.sweden-martina.com
**Use destination and risks class**

In accordance with Directive 93/42/EEC implemented in Italy with L.D. 46/97 of 26/03/97, Annex IX, Sweden & Martina identifies the prosthetic components and surgical instruments described in this manual as medical devices and identifies their risk class as shown in the table below.

In particular, the prosthetic components are medical devices intended to be use in the oral cavity. The functions of the prosthetic components are:

- the reconditioning of gums (healing abutments, long lasting devices);
- the anchorage of dental implants for the support of dental prosthesis (temporary and final posts and related fixing screws, long lasting devices);
- the impression taking (transfer and related fixing screws, temporary use devices, with certified duration not superior than 60 minutes consecutive).

Prosthetic components are single use products. Single use means that each individual device may be used just once, on a single patient. It is common practice for prosthetic components to be tried in the patient’s mouth several times and then sent back to the dental technician for final restoration. This practice is valid and does not alter the single-use concept, provided the same prosthetic component is always used by the same patient and him/her alone. In the case of multiple restorations, it is important that the same component is always used in the same position and connected to the same implant, i.e. that the components are not switched within the same restoration project. Failure to comply with these indications may compromise the precision of the work. Any reuse in other patients must be considered off-label use and in such cases, Sweden & Martina declines all responsibility.

The instruments are medical devices destined to be used in the oral cavity, for temporary use (duration not superior than 60 minutes consecutive), re-usable. The function of the instruments is the tightening and the unscrewing of all the connection screws (surgical cover screws, healing abutments, posts screws, abutments, prosthetic screws, transfer screws, etc.)
### General Indications

All the devices listed, though destined to be used on all those persons who present the suitable therapeutic indications, have to be used exclusively by professional medical personnel with the needed qualifications and by odontologists in the field of the prosthesis preparation.

**Special warnings**

When tightening transgingival abutments, post screws or prosthetic screws, always use the tightening torques indicated below: excessive tightening torques can weaken the screws’ mechanical structure and compromise restoration stability, with potential damage to the implant connection.

### Device Classification Pack Rule

<table>
<thead>
<tr>
<th>Device</th>
<th>Classification</th>
<th>Pack</th>
<th>Rule Annex IX</th>
<th>Risk Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healing abutments</td>
<td>Long-term, invasive, surgical</td>
<td>Single use, non-sterile</td>
<td>8</td>
<td>2B</td>
</tr>
<tr>
<td>Transfers</td>
<td>Short-term, invasive, surgical</td>
<td>Single use, non-sterile, provided with the connecting screws</td>
<td>7</td>
<td>2A</td>
</tr>
<tr>
<td>Transfer screws</td>
<td>Short-term accessories of invasive surgical medical devices</td>
<td>Single use, non-sterile</td>
<td>5</td>
<td>2A</td>
</tr>
<tr>
<td>B.O.P.T. temporary posts for the realization of temporary prosthesis</td>
<td>Long-term, invasive, surgical</td>
<td>Single use, non-sterile, provided with the connecting screws</td>
<td>8</td>
<td>2B</td>
</tr>
<tr>
<td>Titanium straight and angled posts</td>
<td>Long-term, invasive, surgical</td>
<td>Single use, non-sterile, provided with the connecting screws</td>
<td>8</td>
<td>2B</td>
</tr>
<tr>
<td>Posts connecting screws</td>
<td>Long-term accessories of invasive non-surgical medical devices for use in the oral cavity</td>
<td>Single use, non-sterile</td>
<td>5</td>
<td>2A</td>
</tr>
<tr>
<td>Analogs</td>
<td>Non-invasive medical device</td>
<td>Single use, non-sterile</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Drivers, screwdrivers and extension</td>
<td>Invasive surgical instruments for temporary use (for less than 60 minutes at a time), intended to be connected to an active medical device</td>
<td>Reusable, non-sterile</td>
<td>6</td>
<td>2A</td>
</tr>
<tr>
<td>Drivers/ screwdrivers, hand knobs, parallelism pins</td>
<td>Invasive surgical instruments for temporary use (for less than 60 minutes at a time), not intended to be connected to an active medical device</td>
<td>Reusable, non-sterile</td>
<td>6</td>
<td>1</td>
</tr>
</tbody>
</table>

All the devices listed, though destined to be used on all that persons who present the suitable therapeutic indications, have to be used exclusively by professional medical personnel with the needed qualifications and by odontologists in the field of the prosthesis preparation.

### Recommended Torque

<table>
<thead>
<tr>
<th>Description</th>
<th>Recommended Torque</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical connecting screws, healing abutments</td>
<td>(manually) 8-10 Ncm</td>
</tr>
<tr>
<td>All prosthetic screws</td>
<td>20-25 Ncm</td>
</tr>
<tr>
<td>Transfer connecting screws</td>
<td>(manually) 8-10 Ncm</td>
</tr>
</tbody>
</table>
Maintenance

Some implant restoration-related complications are reported in the literature. These complications may lead to a loss of osseointegration and implant failure. Correct maintenance by the patient, good home dental care and regular sessions with a professional hygienist increase the device's service life. Complications such as the pull-out of screws that fasten the restoration to the implants or bone reabsorption causing the loss of the mucosal resting surface in patients with removable restorations can be easily prevented with regular check-ups. If post or prosthetic connecting screws are needed, these operations must be performed by the practitioner using suitable devices with torque tightening control. The calibration of these devices should be checked regularly.

In the event of complications of this kind, patients should contact their practitioner as soon as possible, so that the restoration can be repaired and functionality restored. A delay in contacting the doctor may lead to fractures in the connecting screw and the prosthesis, in the first case, and to implant failure in the second case, which could impair the rehabilitative result. Practitioners must make this clear to their patients.

Complications can be of a biological nature (loss of integration) or mechanical nature (fracture of a component due to overloading). If there are no complications, duration depends on the devices and the whole restoration system depends on mechanical resistance in relation to the fatigue accumulated by the device.

Any de-cementing of cement-retained crowns or bridges secured using final cement, such as to transmit shocks to the implant structures, can lead to the failure of the same. Sweden & Martina has conducted 5,000,000-cycle fatigue resistance tests on its implant-post-connecting screw sets. The sets passed the test. Fatigue tests are conducted according to applicable standards and further assessed by means of finite element calculations.
Caution!!! All prosthetic components for dental implants and all instruments are sold NON-STERILE. Before use, all the items must be cleaned, disinfected and sterilised according to the procedures validated by Sweden & Martina S.p.A. These processes must also be performed before intraoral use, i.e. before each use for any test phases and in any case before final restoration loading. Repetition of the processes described in this paragraph does not alter the characteristics of these devices. The failure to follow these instructions may lead to cross infections.

a. Cleaning: containers and transport to be used for washing; there are no special requirements. In case of automatic cleaning, use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer’s instructions concerning concentrations and washing times. Use demineralised water to prevent the formation of stains and marks. When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually. When cleaning manually: use a suitable neutral detergent and follow the manufacturer’s user instructions. Brush the products with a soft-bristled brush under plenty of running water. Use the brush to apply the detergent to all surfaces. Rinse with distilled water for at least four minutes. Make sure plenty of running water passes through any holes. After rinsing, dry the devices thoroughly and place them inside suitable sterilisation bags. Do not exceed 120°C when performing a drying cycle in a washing and disinfection appliance.

b. Sterilisation: iPlace in a vacuum autoclave and sterilise as follows: Temperature = 121 – 124°C, with autoclave cycle of at least 20 minutes and drying cycle of 15 minutes.

c. Storage: after sterilisation, the product must remain in the sterilisation bags. The bags should only be opened immediately prior to reuse. In normal conditions, sterilisation bags maintain the sterility of the contents, unless the wrapping is damaged. Therefore, do not use components if the bags in which they were kept are damaged, and resterilise in new bags before using them again. The storage time of products sterilised inside the bags should not exceed that recommended by the manufacturer of the bags. The product must be stored in a cool dry place, away from direct sunlight, water and heat sources.
GENERAL INDICATIONS

Cleaning, disinfection, sterilisation and storage of the dynamometric ratchet CRI5

The processes described below must be performed before use and before each subsequent operation. Repetition of the processes described in this paragraph has minimal effect on the wear of the device. The failure to follow these instructions may cause cross infections. Containers and transport to be used for washing: there are no special requirements. As soon as possible after each use, the key must be placed in a container filled with a disinfecting/cleansing solution and covered with a cloth. This prevents the desiccation of the contaminating agents coming from the patient, and dissolves them, thus making cleaning easier and more effective. Completely disassemble the key as shown below:

Completely unscrew the torque adjustment screw and remove the spring inside the handle of the ratchet body. Do not separate the spring from the pin that acts as a stop.

Use the hexagon tip at the bottom of the torque adjustment screw to unscrew and completely remove the connecting screw of the cover from the side marked "OUT". Exert a light pressure in order to avoid damaging the hexagon tip.

After removing the cover, pull out the two components contained inside the ratchet head: the toothed pawl wheel and wheel stop tooth.

In case of manual cleaning, clean the outer and inner surfaces of the instrument mechanically under hot water with a soft bristled brush. Inject hot water using a needleless syringe to wash the hard-to-access holes of the head and the area around the pawl wheel and wheel stop. If necessary, proceed in the same way for the inside of the handle and of the torque adjustment device. Use a suitable neutral detergent and follow the manufacturer’s user instructions. Use demineralised water to prevent the formation of stains and marks. During this cycle, avoid contact between the pieces because this causes the machined surfaces to deteriorate, and consequently, loss of precision of the torque measurement. When draining, check the recesses of the devices, holes, etc. to make sure all residues have been completely removed. If necessary, repeat the cycle or clean manually.
**Please note:** blood residues or other deposits reduce the efficacy of the sterilisation process, which is why it is important to clean thoroughly. During cleaning, avoid sprays or jets of liquid and adopt adequate protections. Avoid contact between this instrument and other nickel-plated instruments. The pieces must be reassembled prior to sterilisation. Dry the parts, lubricate the functional areas lightly and reassemble the key as shown in the figures below. Too much lubrication may cause the surfaces of the instrument to resurface during sterilisation. Use only the lubricant supplied.

After lubricating the parts shown in the figure, insert the two elements of the ratchet head according to the following sequence: the toothed pawl wheel and then the wheel stop tooth.

Lubricate the contact areas between the tooth of the pawl wheel and the pin of the wheel stop tooth.

Once parts 2 and 3 have been lubricated and inserted in the head of the ratchet body, position the cover and turn the ratchet body from the “OUT” side. Tighten the screw with the hexagon tip of the torque adjustment screw.

Lubricate the spring inside the ratchet handle as shown in the figure. Assemble the torque adjustment screw, making sure the instrument functions properly. Manually activate the pawl wheel.

**Sterilisation:** in a vacuum autoclave, proceeding as follows: Temperature = 121 – 124 ºC, with autoclave cycle of at least 20 minutes and drying cycle of 15 minutes. This procedure is important in order to preserve the precision of the instrument within a tolerance of ± 3.5Ncm. Operate the torque and insertion mechanism to check their proper functioning. Remove any traces of lubricant from the outer surface of the key. Place the device in suitable sterilisation bags. It is recommended to practice the disassembly and reassembly operations, following the instructions.
Responsibility for defective products and warranty terms

Optimal patient care and attention to their needs are necessary conditions for the success of implantation procedures and, therefore, patients must be carefully selected and informed of the associated risks and obligations connected with the treatment and encouraged to cooperate with the odontologist in the interests of the success of the same treatment. The patient must, therefore, maintain good hygiene, which should be confirmed during check-up appointments, guaranteed and recorded and the practitioners instructions and orders shall be observed. The warranty only covers manufacturing defects as long as the faulty piece is identified by the article code and batch number and returned within the validity period of the warranty.

The warranty terms are available on the website www.sweden-martina.com

Warning – Warranty limits

The prosthetic components manufactured by Sweden & Martina are for anchoring to dental implants and prosthetic instruments also manufactured by Sweden & Martina. Use of non-original components limits the responsibility of Sweden & Martina S.p.A. and renders the product warranty void.

Prosthetic components must be fastened to the implants using dedicated instruments. When tightening prosthetic components, use original instruments manufactured by Sweden & Martina. Sweden & Martina declines all responsibility for use of any non-original instruments.

The instruments manufactured by Sweden & Martina are designed for use with dental implants and prosthetic components also manufactured by Sweden & Martina. Use of the instruments for working with implants other than those manufactured by Sweden & Martina limits the responsibility of Sweden & Martina and renders the product warranty void. Sweden & Martina declines all responsibility for use of any non-original instruments.

Disposal

If removed from the oral cavity due to biological or mechanical failure, the implant fixtures must be disposed of as biological waste. The surgical instruments are made of small components, mostly metal. They may be disposed of as such. If dirty, they must be disposed of as biological waste. In general, the local regulations apply.
## Key to symbols used on the implant packs

<table>
<thead>
<tr>
<th>Description</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caution, please see instruction leaflet</td>
<td>![Exclamation Mark]</td>
</tr>
<tr>
<td>Batch number</td>
<td>![Lot]</td>
</tr>
<tr>
<td>Code</td>
<td>![Refer]</td>
</tr>
<tr>
<td>Non sterile product (only prosthetic components and surgical instruments)</td>
<td>![Non Sterile]</td>
</tr>
<tr>
<td>Single use product, do not reuse</td>
<td>![Exclusion Mark]</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>![Manufacturer]</td>
</tr>
<tr>
<td>Consult the instruction leaflet</td>
<td>![Information]</td>
</tr>
<tr>
<td>CE conformity marking, class 1 products</td>
<td>![CE]</td>
</tr>
<tr>
<td>CE conformity marking, class 2a and 2b products</td>
<td>![CE with 0476]</td>
</tr>
<tr>
<td>American federal law restricts this device to sale by or on the order of a dental surgeon</td>
<td>![Rx Only]</td>
</tr>
</tbody>
</table>

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