

DENTATUS MTI - Monorail™ Transitional Implant System

The Installation of MTI Implants and the Monorail Fabrication of Restorations

- Section A.*** Instructions for the chairside fabrication of restorations
- Section B.*** Impression and customized laboratory fabrication of fixed and removable prosthesis

Dentatus AB Sweden, is certified to ISO 13485/ EN 46001.
The product is CE marked by the Notified Body ID 0510

US Pat. #5,575,651, 5,788,492 & Foreign Pat. Pending

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We are pleased that you have joined the growing number of professionals that use the Dentatus Monorail System for the immediate replacement of the patients' missing teeth.

The implant and restorative specialists can now provide a separate, more effective service by immediately constructing a splint that immobilizes the MTI Implants and protects the patient's surgical sites.

The restorative procedures can follow immediately with a chairside constructed restoration, by retrofitting the patient's denture or fabricating a fixed provisional restoration.

MTI supported restorations may be used for any length of time as decided by the professional care provider. They can be unscrewed thereafter without bone damage and without discomfort to the patient.

To alleviate your concerns for selecting safe implant products and using professionally validated procedures, we are pleased to provide you with the following information.

The earliest Dentatus pure Titanium tempered metal anchor series, introduced in 1970, have subsequently proven to be ideal for implant support and highly adaptable to soft tissue.

The Transitional Implants were initially tested on non-human primates and canines by university teams of specialists. The MTI use and function was critically appraised in peer reviewed literature by dentists in the U.S. and abroad. To-date, more than 50 published papers describe the MTI usefulness and attest to its safety and great patient satisfaction. The Patented MTI Implant - Prosthetic System, in use since the early 90's is now considered the "Gold Standard" of implantology. We are proud of our past achievements and look forward to hearing your comments and observations in order to satisfy your future professional requirements.

For further information, you may want to check in greater detail, some of the selected references listed in this manual.

*Sincerely,
Bernard Weissman, President*

The Multiple Use of the MTI - Monorail System

The initial, primary use for MTI was to provide patients with immediate restorations and avoiding stress on the submerged implants during the lengthy implant restorative intervals. Progressively, MTI has been found to have a much greater, profound impact in the restorative practice.

Restorative dentists have in time realized that the initial temporary restoration served yet a wider function in the reconstructive procedures. It made it possible to check and confirm occlusal relations, tooth form, length, and shade, as well as obtain the patient's approval.

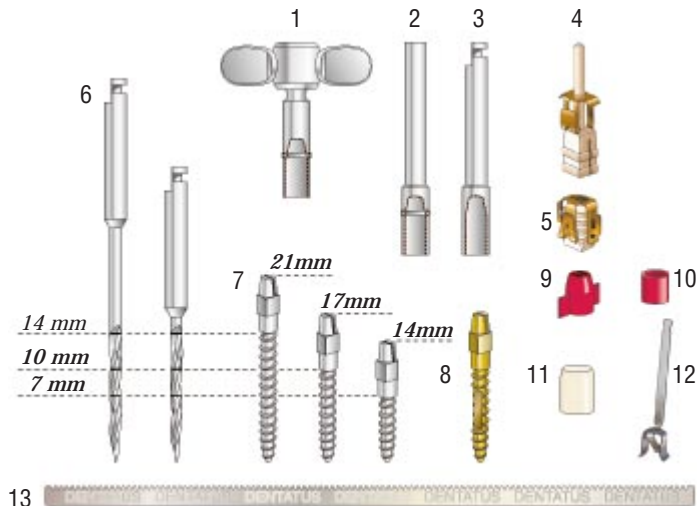
These measures did prevent costly corrections and avoided irreversible, less than ideal restorative results.

MTI is now used in the following procedures.

- *Chairside retrofitting of dentures over the MTI splint retained with soft liners.*
- *Immediate replacement of individual small and quadrant missing teeth.*
- *Stabilizing stents for precise osteotomy site selection.*
- *Stabilizing bone grafts and securing membrane barriers.*
- *Emergency support and repair of failing key abutments.*
- *Anchors for orthodontic tooth and orthognatic jaw repositioning.*

MTI Monorail Components

1. Winged Socket Key
2. Paralleling Extension Rod
3. R/A Hpc. Driver
4. Modular Coping
5. Singular Coping
6. Profile Drills - Long & Short
7. Ti Implants - 14, 17, & 21mm
8. Lab Analog
9. Impression - Casting Coping
10. Gingival Protective Spacer
11. Comfort Cap
12. Bar Spacer Clip
13. Ti Connective Bar
14. Flexible Splint Form - Long & Short

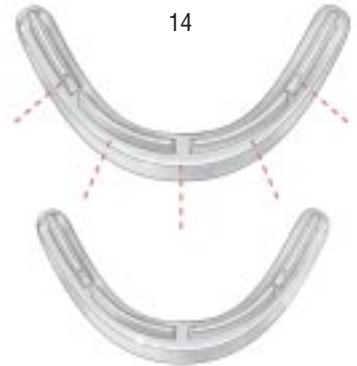




Monorail Modular Coping with a Suspension Tab that can be oriented facially or lingually for placing the second Ti Bar.



Monorail Singular Coping with an Internal Crossbar and Suspension Tabs for placing bars facially and lingually.



Flexible Short and Long Splint Forms can be scissor-notched to fit a wide range of ridge forms.

Cautions and Notes

The Monorail MTI Implants, prosthetic components and accessories are delivered factory-clean in non-sterilized condition. Components must be removed from its wrapping and sterilized in strict compliance with surgical protocols and requirements. The components withstand autoclaving at 135° C and, where applicable, may be immersed in most cold sterilizing solutions.

The MTI Implant must be firmly inserted into the R/A Driver or Winged Socket Key to prevent accidental swallowing or aspiration.

To prevent enlargement of the canals and possible damage to the bone, the MTI needlepoint drills must be used for no more than 6 - 8 osteotomies especially in D-1-2 hard bone.

The MTI Implants should be immediately immobilized by a restoration cemented and left in place during the healing stages and bone remodeling intervals. Patients must be informed that the Dentatus MTI Implants are intended for transitional or longer-term use as decided by the professional care provider.

The professional care provider should obtain the patient's signed consent before initiating implant treatment procedures.

US Federal law restricts the use of this device by anyone other than a licensed dentist or someone with a licensed dentist's consent.

For maximum safety, the MTI - Monorail components should be selected and sterilized in advance and made available at the operating site as needed.

The MTI Implants may not be re-used and must be discarded immediately after their removal.

The printed guidelines including the precautions and notes are to be regarded as additions to accepted professional standards and safe practice.

Introduction for the Installation of MTI Implants and the Fabrication of Monorail Supported Restorations

A diagnostic examination with radiographs and C.T. scans, including current articulated models, are the primary requirements for achieving the planned results.

Diagnostic wax up is duplicated in a hard stone model that reflects the anticipated functional and aesthetic objectives and for making clear replicas. The vacuum replicas should extend over the retromolar pads and tuberosities for more accurate orientation when placing it in the patient's mouth.

The replica is indispensable for visual observations of the implant site and the space required for the Monorail prosthetic components and is used to make, most economically, a chairside fabricated restoration for the immediate replacement of the patient's missing teeth.

Note:

After the initial healing and suture removal, a customized laboratory fabricated restoration can be made with an impression and Monorail Analogs for transfer of the MTI jaw relation to a master cast.

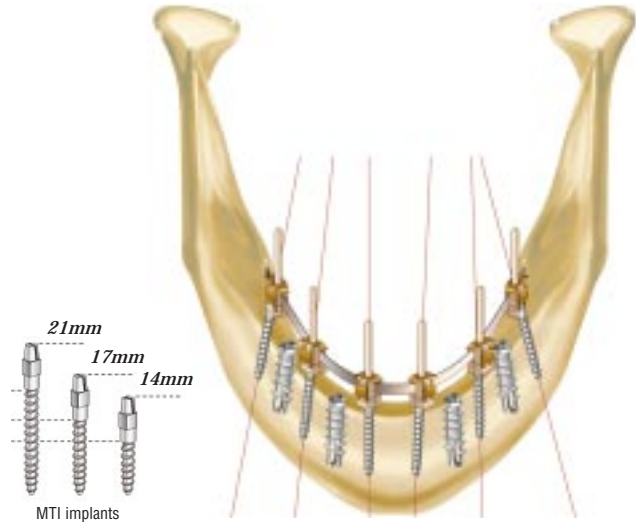
The implants' position, spacing, angulation, and depth are carefully noted and marked on the ridge. The MTI Implants should be placed 1.5 - 2mm from adjacent implanted fixtures allowing additional space for wider healing caps.

The new Monorail prosthetic components are designed to accommodate moderately divergent implant angles and heights in a compensating manner. When imbedded in the resin, the components create a stress-free restoration that is easy to seat and remove.

The load-bearing Ti Bars bisecting the center of the MTI Implants long - axis distribute evenly masticatory loads, without the undesirable pressure on the ridge and the submerged implanted fixtures.

“For multi-unit unilateral restorations, the MTI Implants should be placed, when possible, in a cross ridge alignment. The restoration should be firmly cemented and left in place during the bone remodeling intervals.”*

* *Dennis Tarnow, Professor and Chairman, Ashman Department of Implant Dentistry, New York University, College of Dentistry, New York, NY.*

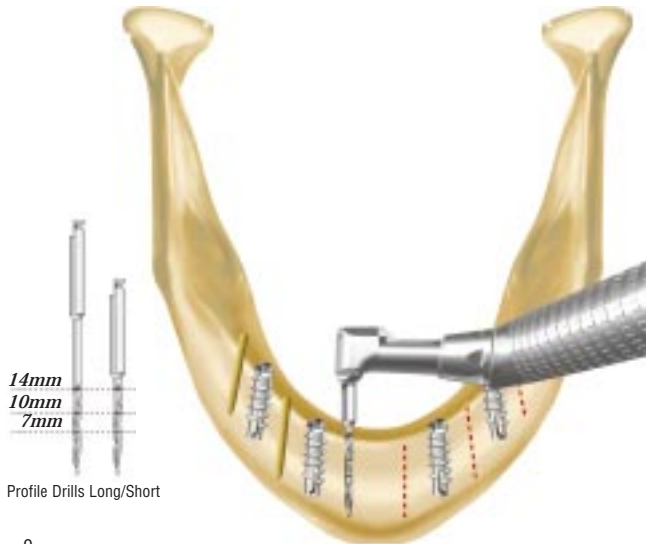


Section A.

I.

The channels are made with the MTI depth marked profile drill at approximately 800 - 1000 rpm with copious amounts of bio-compatible sterile water or saline solution. In hard D1, 2 mandibular bone, the channels are enlarged by multiple 3 - 4 drill entries to the full marked depth to prevent accidental shearing of the implant. In the maxilla D3, 4 porous bone, the channels are made with only 1 entry and to half of the intended depth. The self-threading MTI Implants will advance into the porous bone to the full depth creating firm intimate anchorage.

The sharp MTI needle-point drills are used for making the channels as well as for pre-drilling positions for large implant fixtures. Excessively used dull drills must be discarded as they may enlarge the channels and possibly cause tissue necrosis by overheating the bone.

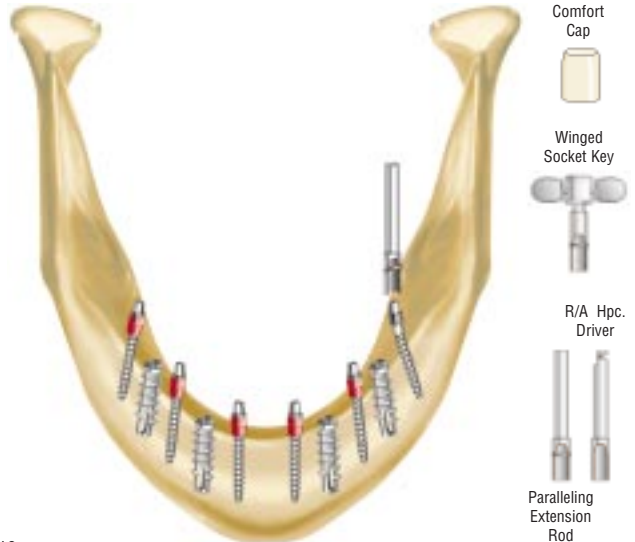


II.

The Monorail System accommodates considerable mesio-distal, buccal-lingual divergent angles. Gross inter-arch misalignments can be corrected with the Paralleling Guide Rod with its cross bar to prevent the deformation of the implant slot. The minor angle correction can be made without damage to the MTI Implant or impairing its function.

The MTI R/A Driver with a cross bar is used for the initial placement of the implants to a depth of 3-5 mm. The installation is completed manually with the Winged Key which is also used for aligning the slots with the crest of the ridge.

The soft Comfort Caps secured with temporary cement are used for protecting the patient's tongue and cheeks. They should be used only during an overnight period and during Surgical-restorative interoffice travel time. The soft Comfort Caps may not be used for supporting restorations.



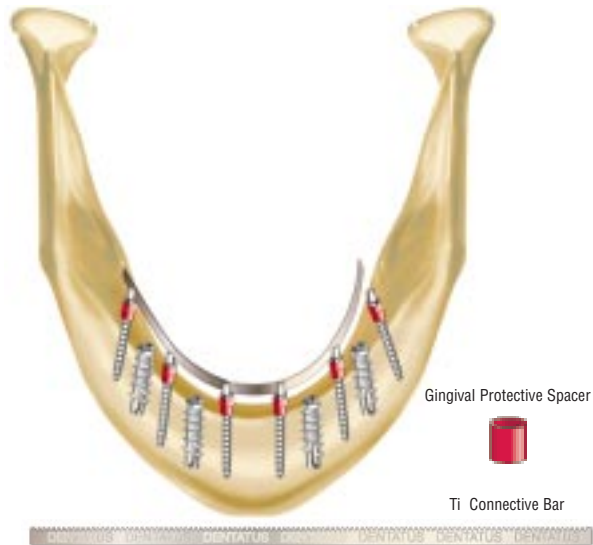
III.

Before using the Modular Copings, the spacers are placed to fit under the narrow neck, and covering the implant's square head. The spacers must not interfere with the complete seating of the bar in the slot.

The Ti Bar with the smooth edge facing the ridge is formed with finger pressure to follow the crest of the ridge. The bar is initially used to test the MTI angle position, slot alignment, and vertical height. In greatly variable implant heights, the Singular Copings are used that become interconnected externally with the Ti Bars.

Notes:

To prevent soft resin tissue contact and possible suture entanglement, a half-inch wide thin surgical adhesive tape should be adapted over the MTI heads in a buccal/lingual direction over the ridge before placing the Protective Spacers.



IV.

The new Monorail Modular Copings are used in ideally aligned MTI Implants and level height cross-arch relation. The copings' Suspension Tab can be oriented either lingually or facially, depending on the available space. The copings, are placed over the bar in a common parallel relation before the Metal Clips are pushed down to engage the protective sleeves in a clamp-type manner.



V.

The second reinforcing bar is placed in the Suspension Tabs in a straight line and the extension rods are clipped off. For operative convenience the assembly can be more firmly secured with a monomer-powder brush application technique.

The Modular and Singular Copings may be combined to accommodate all variable conditions and both systems provide a very strong twin-bar metal resin laminated foundation.



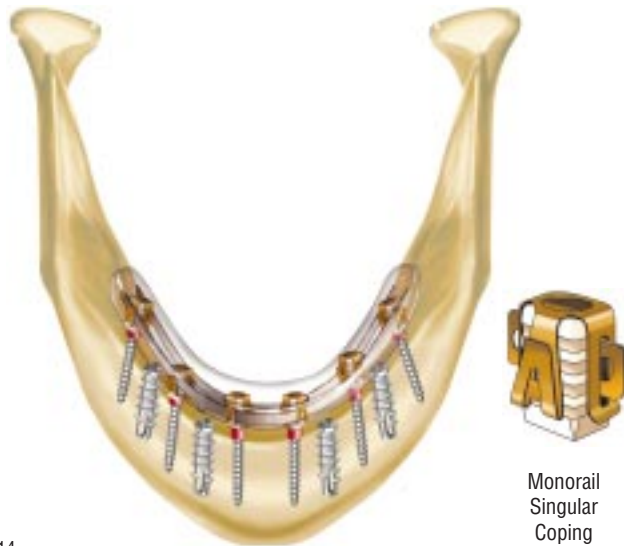
VI.

The Monorail new Singular Copings, adaptable for all restorations, are particularly useful for smaller, and multi-unit bridges and in narrow spaces without limitations of MTI height and orientation. The copings, with its internal occlusal bar-stop, are interconnected externally with the Ti Bars, creating a strong long-term resin/metal laminated foundation, for large, intermediate and small units without the need for cast metal frames.

The assembled components and bars are attached with self-curing resin. The resin is packed into the Monorail Flexible Splint Form allowing it to reach the pre-setting tacky consistency. It is placed over the components in a compressive manner and must not be removed before it is fully polymerized. The splint is reduced in size for attaching the dentate section of the restoration.

Note:

The Bar Spacer Clips, optionally available, are placed in strategic areas to hold the bars evenly in place. The carrying handles are separated by twisting them off after their installation.



Monorail
Singular
Coping

VII.

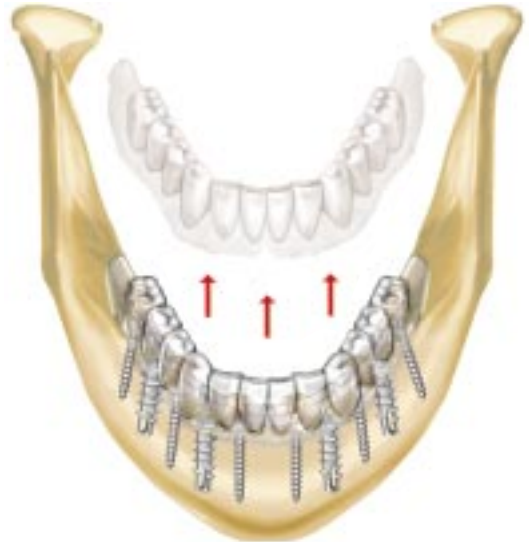
A very practical chairside fabrication technique is used with the flexible vacuum formed replica copied from the diagnostic wax up duplicated model. It is placed over the finished smooth splint, marking its position for accurate placement. It is filled with tooth-color self-curing resin and aligned over the splint and markings. The replica is removed, the sharp edges are finished smooth, and the polished restoration is firmly cemented in place.

An alternate method is to use a laboratory fabricated, wide-base hollow-type bridge to fit passively over the splint that is attached with tooth-colored self-curing resin.

For complete laboratory restorations the Monorail Transfer Copings can be used for duplicating the MTI positions on the Master Cast.

Note:

When making splints, bridges, and relines, Protective Spacers must be used to prevent the soft-resin from interlocking the restoration.



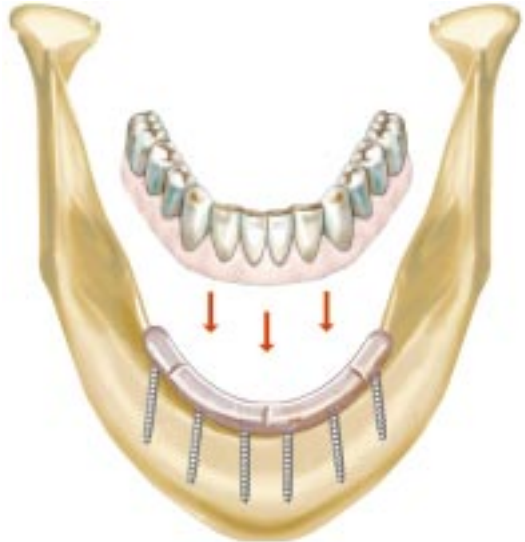
VIII.

Immediate Splinted Stabilization for retrofitting existing and also new removable dentures.

1. The MTI Implants are strategically placed through the tissue into the bone for the support of a low profile chairside constructed splint.
2. The splint is reduced to a gentle ovoid-form and creating indexing grooves for exact denture placement. It is smoothly finished and firmly cemented in place. The existing functional denture is relieved to fit over the splint with additional space for attaching the soft-reline material.
3. Excess soft material is removed and the interior may be relieved to create a retentive form for gentle removal and replacement of the denture by the patient. See pgs. 22-23.

Note:

After healing and suture removal, a customized laboratory restoration may be constructed. The Monorail Impression Copings are used with conventional impression techniques for replicating the implant jaw positions on the Master Cast.



SECTION B.

MTI - Monorail Prosthetic Procedures

IX.

Heavy-body elastic impression material is used to index and firmly hold the copings in the impression. The copings are fully inserted and the impression material is injected carefully underneath the copings followed by placing the impression tray for duplication of the ridge area.

The Protective Spacers are not used for taking the impression.

Note:

The Impression Casting - Copings are used for waxing patterns, for cast resin-ceramo-metal crowns and frames.

The patterns are waxed with the Gingival Protective Spacers in place. They are removed before investing the patterns for casting them in metal of choice.



Impression
Casting -
Coping With
Wax Pattern
Outline



X.

The new Monorail Singular Copings greatly simplifies the laboratory fabrication of close-fit durable restorations. The brass analogs inserted carefully into the impression firmly indexed copings are sealed for making the master cast. The Protective Spacers are placed over the slimmer neck to fit under the square head of the implant to prevent soft resin from interlocking the restoration.

The analog positions on the Master Cast must not be altered or changed.

Note:

Intra-oral registration is followed in a manner used in conventional prosthetic procedures.



Lab
Analog

XI.

The Singular Copings with the internal occlusal bar-stop are placed to contact the bottom of the MTI slot. The assembly with the Ti Bars are placed lingually and facially through the suspension tabs.

The components, that become attached with self-curing resin, create a strong, resilient laminated foundation.

Note:

Only Monorail Singular Copings are used in customized laboratory produced restorations. When properly following the instructions, it will not require adjustment for replicating the accurate fit over the MTI Implants.



Monorail
Singular
Coping

XII.

Self-curing resin is compressed into the pre-fab Monorail Flexible Splint. After reaching a pre-setting tacky consistency, it is compressively seated over the assembly. The splint and the splint-form should not be removed before the resin is fully polymerized to a hard state.

The splint is reduced as needed without exposing the copings.

Note:

The polymerization may be enhanced under water-pressurized conditions.

When heat-cure resin must be used, the coping and the assembly must be securely sealed in a manner that no resin will enter into the coping's interior.



XIII.

Fixed Provisional Restorations

A separately constructed hollow shell-type bridge is tested to fit passively over the splint. Before attaching the bridge, the splint must be fully seated and sealed to the model with wax to prevent resin from entering into the interiors of the coping. The shell is attached to the splint with tooth-color self-curing resin and allowed to polymerize fully before it is removed.



XIV.

Removable Dentures

For constructing and retrofitting a functional, existing denture, the separate splint is refined to a minimal height and to a gentle ovoid form with shallow index locating grooves. An impression with the splint in place may be used for making the master cast. The denture tissue-side is relieved to fit passively over the splint with additional space for a chairside or lab attached soft reline tissue surface.



XV.

Dentatus Monorail Splints create long-term metal-resin laminated support for the over-dentures.

The soft reline materials can be finely adjusted to prevent damaging stress by the patient's repetitive removal of the prosthesis.

Easily renewed soft relines offer patients secure, uninterrupted use of the prosthesis.



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In keeping with the policy to serve our customer needs, we have placed your name on our preferred mailing list. You'll be informed periodically of new developments, product and technique changes, and update you with pertinent professional literature related to the Dentatus MTI Monorail System.

*You can e-mail us at dentatus@dentatus.com
or find us on the web at www.dentatus.com.*

Dentatus AB
Jakobsdalvagen 14-16
SE126 53 Hagersten
Sweden
Tel.: + 46-8-546-509-00
Fax.: + 46-8-546-509-01



Dentatus USA, Ltd.
192 Lexington Ave.
New York, NY 10016
Telephone: 212-481-1010
Fax: 212-532-9026
Toll Free: 800-323-3136