

**Dentatus AB**  
Finspångsgatan 42,  
SE-163 53 Spånga, Sweden

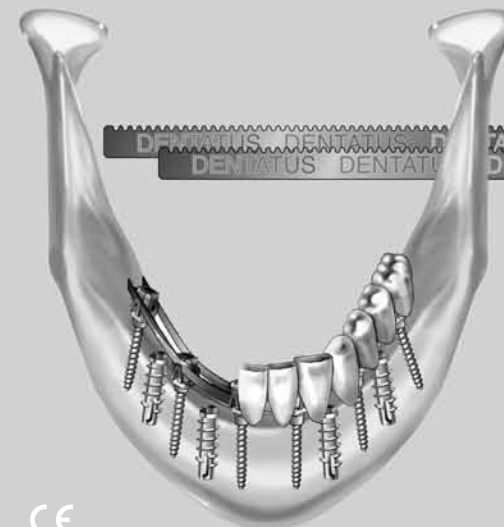
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info@dentatus.se

**US** + 1 212 481 1010  
dentatus@dentatus.com

BL-6299-04



## ***DENTATUS MONORAIL™ IMPLANTS***

***For Immediate Restorations***

### ***SECTION A***

Installation of Monorail Implants and  
Chairside Construction of Restorations

### ***SECTION B***

Laboratory Construction of Fixed  
Bridges and Removable Dentures

### ***INSTRUCTIONS***

Dentatus AB Sweden,  
is certified to ISO9001/ ISO13485

US Pat. #5,575,651, 5,788,492 & Foreign  
Pat. Pending Printed in USA 05/13

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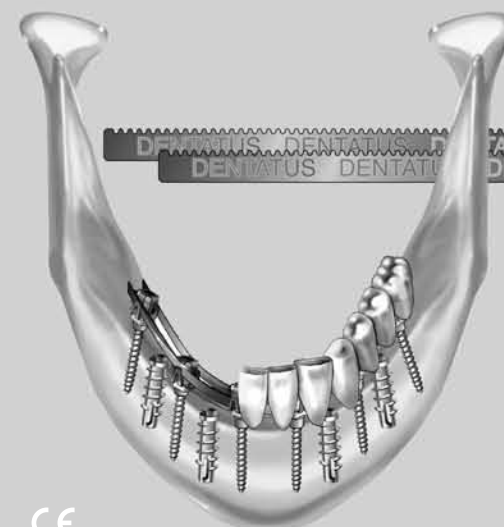
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***The New Dentatus Monorail Fast-Track System  
For expanded use in restorative procedures***

- Immediate in-office replacement of missing teeth
- Retrofitting and stabilizing existing dentures
- Emergency repairs of failing restorations

*In keeping with the Dentatus policy of customer relations, we have placed your name on our preferred mailing list.  
We will send you the latest clinical and technical published information and  
bring to your attention Monorail’s continuously evolving use in the general practice.*

***You can also reach us via e-mail at [dentatus@dentatus.com](mailto:dentatus@dentatus.com)  
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The patented Dentatus Modular Transitional Implant System, in use since 1993, are validated in over 50 published clinical papers and in university based histological studies. The authors, implantologists, prosthodontist and restorative dentists confirm their overall effectiveness, safety and outstanding patient approval.

Monorail is an intergrated implant-prosthetic system for chairside-made immediate restorations. The resin/metal reinforced splint provides a strong foundation for fixed full, quadrant, and single teeth and for retrofitted dentures. The denture, reduced to seat on the low-profile firmly cemented splint, is resurfaced with a soft-liner for gentle stress-less fit and removal of the over-denture.

Additionally, Monorail is highly effective for bone augmentation and sinus-lift procedures and for emergency repairs with quick replacement of key failing abutments and implant fixtures.

The Monorail grade 1 pure Ti transitional implant-supported restorations are reported to be kept in place and used for periods of time decided by the patient's professional care provider.

When no longer needed, the implants can be removed by backing them out without causing bone damage or patient discomfort.

The newest generation Monorail Implant Prosthetic Assembly, reduced to 3 easy steps, is user-friendly, practical, and extremely rewarding. Monorail makes implantology accessible to more patients with thin insufficient ridge support and other limiting disabilities and/or restricted financial resources.

Dentatus continues to maintain the leadership position with cutting-edge products and integrated systems providing elegant, practical solutions for finer dentistry.

Sincerely,  
Bernard Weissman  
President

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***Monorail - The Only Integrated Implant Prosthetic Modality  
For the Immediate Replacement of Teeth***

Monorail immediate fixed restorations have advanced the art of implantology establishing a new high standard for restorative procedures. In addition to providing patients with immediate teeth, the interim restorations can be used to establish and confirm occlusal relations, tooth form, and color that will prevent errors and costly time-consuming corrections in customized laboratory constructed restorations.

Following is the wide range of Monorail problem-solving applications with increased predictability and efficiency:

- Immediate replacement of large quadrant and individual missing teeth.
- Chairside retrofitting of dentures retained with soft liners.
- Stabilizing stents for precise osteotomy site selection.
- Stabilizing bone grafts and securing membrane barriers.
- Emergency repairs and stabilizing failing restorations.
- Orthodontic tooth and orthognatic jaw repositioning.

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Cautions and Notes

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Temp 132° C, Pressure 30 psi, Time 8 minnutes.

However the health facility shall validate its own autoclave steam sterilization machine in accordance with FDA recognized standard.

The Implant must be firmly inserted in the R/A Driver and Manual Socket Key to prevent accidental swallowing or aspiration.

To prevent overheating and possible damage to bone, the Monorail needlepoint drills should be used for only 6-8 osteotomies, especially in D-1 & 2 hard bone.

The Monorail Implants should be immediately immobilized by a restoration firmly cemented and left in place during the healing stages and bone remodeling intervals.

Patients must be informed that the Dentatus Implants are designated for transitional use. They may be left in place for extended length of time as decided by the patient's professional care provider. The professional care provider should also obtain the patient's signed consent before initiating the implant restorative procedure.

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

For maximum efficiency and safety, the Monorail components should be selected and sterilized in advance and made conveniently available at the operating site.

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

The printed guidelines, including the Cautions and Notes, are to be regarded as additions to safe accepted professional standards.

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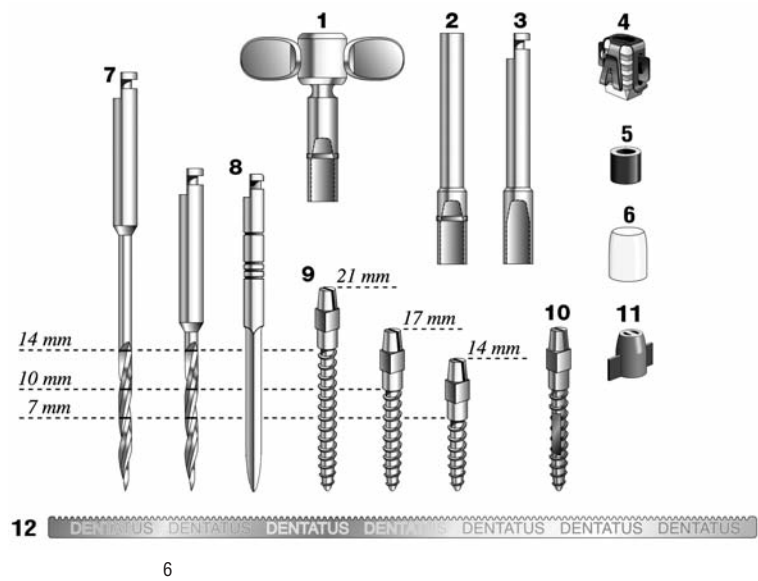
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Monorail Components

- 1. Manual Socket Key
- 2. Paralleling Extension Rod
- 3. R/A Hpc. Driver
- 4. Singular Copings
- 5. Gingival Protective Spacers
- 6. Comfort Caps
- 7. Profile Drills - Long & Short
- 8. Reamer
- 9. Ti Implants - 1.8 Dia. in 3 lengths
- 10. Lab Analogs
- 11. Impression Copings
- 12. Ti Connective Bars
- 13. Flexible Splint Forms - Long & Short

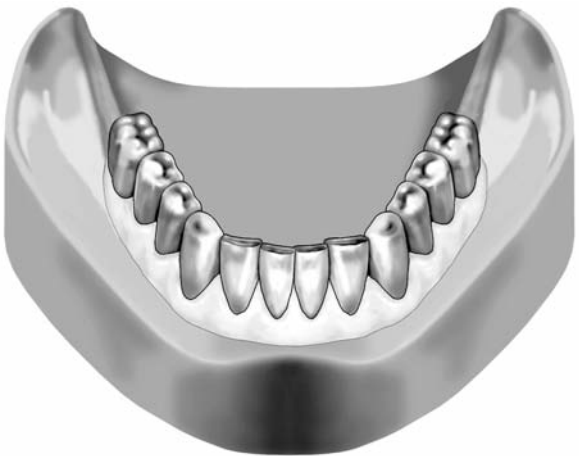


XIV.

Dentatus Monorail metal-resin splint foundations provide strong support for over-dentures.

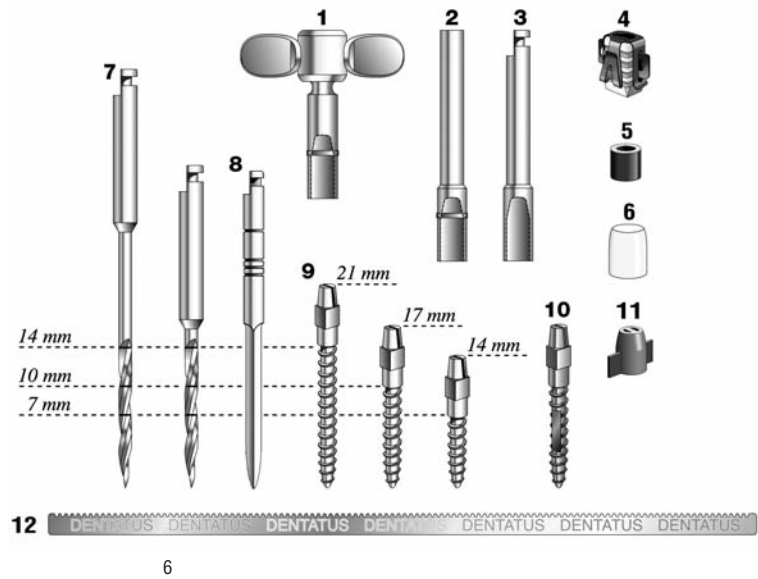
Easily renewable soft relines will provide patients with uninterrupted use of a retentive comfortable prosthesis.

The reline interface can be adjusted and fine-tuned to prevent excessive-pull frictional resistance during denture seating and removal.



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XIII.  
**Construction and Retrofitting of Over-Dentures**

The supporting laminated splint is refined to a minimal height and gentle ovoid-form with shallow indexing grooves for seating the denture. An impression with the splint in place is used to make the Master Cast. The denture's tissue-side is relieved to fit passively over the splint with additional space allowing for a chairside or laboratory installed soft relined interface.

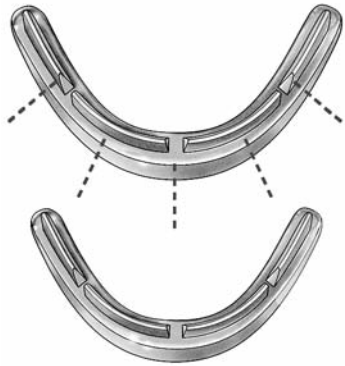


22



Monorail Singular Coping,  
With the internal metal crossbar and  
Suspension tabs for metal bars.

7



Flexible Short and Long Splint Forms  
they can be scissor-notched to fit the  
wide range of upper/lower ridge forms.

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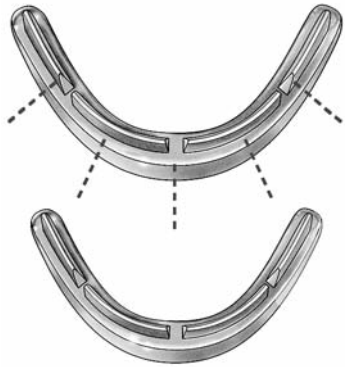


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With the internal metal crossbar and  
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Flexible Short and Long Splint Forms  
they can be scissor-notched to fit the  
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**Advance Preparation: For The Installation of Monorail Implants and Prosthetic Components**

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

A diagnostic wax-up that reflects the anticipated functional and aesthetic objectives is duplicated in a hard stone model for making multiple clear flexible replicas of the dentate-form. The vacuum formed flexible replicas should extend over the stable landmarks of retromolar pads and tuberosities for accurate placement orientation.

The replica is indispensable for visual observation of the implant site and space required for the Monorail prosthetic components. The replica, filled with tooth-color resin, may also be effectively used to construct chairside provisional restorations for replacing instantly the patient's missing teeth.

*The alternate method is to prepare, in advance, a bridge-type wider dentate shell that will be attached over the splint with self-curing tooth-color resin that is reduced to ideal-form after polymerization.*

**Note:**  
*After the initial healing, a customized laboratory restoration can be made with an impression using Monorail transfer copings and Analogs to make the Master Cast.*

**Advance Preparation: For The Installation of Monorail Implants and Prosthetic Components**

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

A diagnostic wax-up that reflects the anticipated functional and aesthetic objectives is duplicated in a hard stone model for making multiple clear flexible replicas of the dentate-form. The vacuum formed flexible replicas should extend over the stable landmarks of retromolar pads and tuberosities for accurate placement orientation.

The replica is indispensable for visual observation of the implant site and space required for the Monorail prosthetic components. The replica, filled with tooth-color resin, may also be effectively used to construct chairside provisional restorations for replacing instantly the patient's missing teeth.

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**XII.**

**Bridge-Type Fixed Restorations**

A separately constructed wider shell-type bridge is tested to fit passively over the splint. The splint must be securely sealed in place to prevent resin from entering into the interiors of the coping. The dentate shell, attached to the splint with heat-cure or self-curing resin, must be fully polymerized before it is removed from the model.

**Note:**  
*When heat-cure resin is used, the splint must be securely sealed in a manner that will prevent any resin to enter into the coping's.*

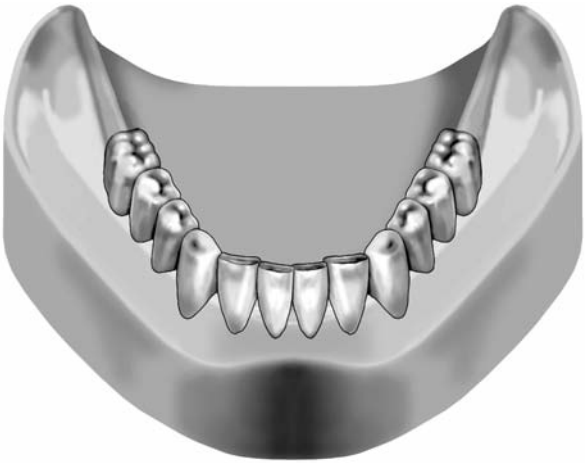


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XI.

Self-curing resin is placed into the pre-fab Flexible Splint. After reaching a pre-setting tacky consistency, it is compressively seated and closely adapted over the prosthetic assembly and the ridge. The splint should not be rocked or removed before the resin has fully polymerized.

The splint may be reduced to a slim low-profile height up to the limit of the bars and copings.



20

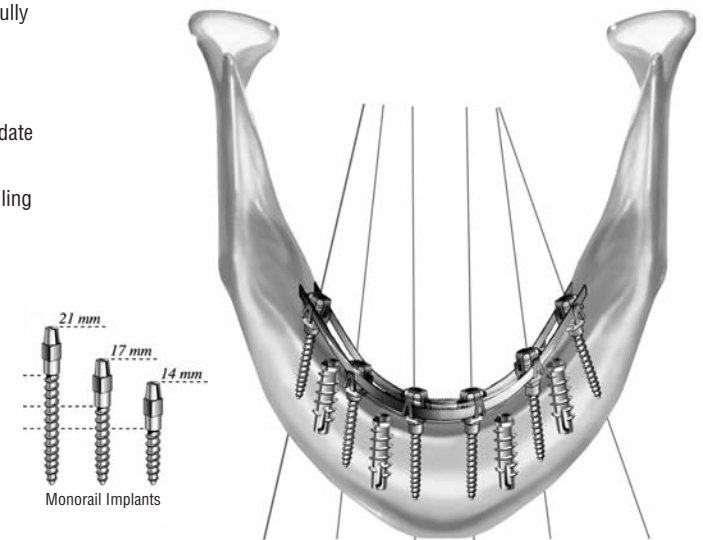
The implants' position, spacing, angulation, and depth are carefully noted and marked on the ridge. The Implants should be placed 2 - 2.5mm from adjacent implanted fixtures allowing additional space for wider healing caps.

The Monorail prosthetic components are designed to accommodate variable heights and moderately divergent implant angles.

The Singular Copings, with internal cross-bars, passively straddling the implant slots reduce and cushion masticatory loads on the mucosa and the submerged implanted fixtures.

"Implants for unilateral multi-unit restorations should be placed, when possible, in a cross ridge alignment. Restoration should be firmly cemented and left in place during the initial bone remodeling intervals."\*

\* Dennis Tarnow, Professor and Chairman,  
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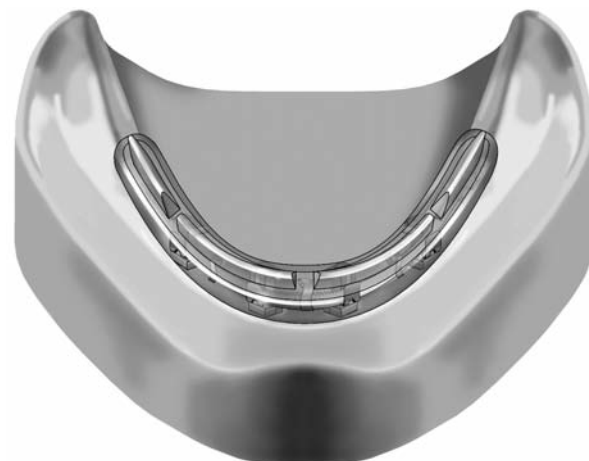


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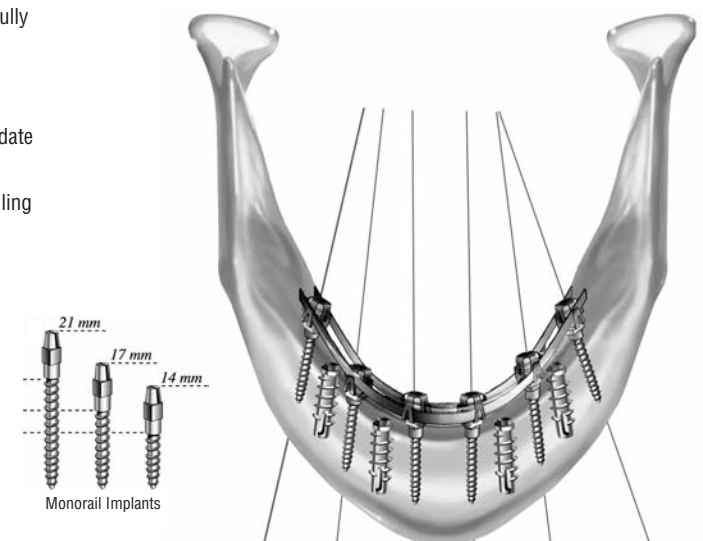
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9

**Section A**

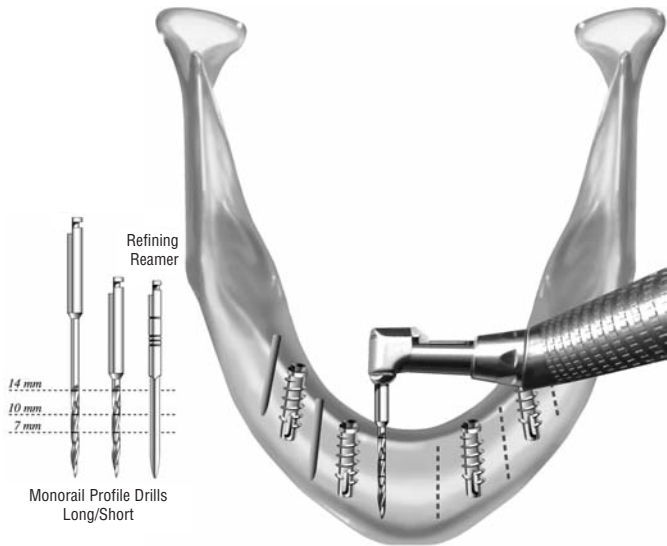
**I.**

The channels are made with the Monorail laser depth marked profile drill at approximately 800 - 1000 rpm with copious supply of bio-compatible sterile water or saline solution.

In hard D1, 2 mandibular bone, the channels are enlarged with the minimally wider Refining Reamer for reducing excessive insertion torque and to prevent accidental shearing of the implant.

In the maxilla D3, 4 porous bone, the channels are made with only 1 drill entry only to half of the intended depth. The self-threading Monorail Implants will advance to the intended depth creating intimate interface bone anchorage.

The Monorail sharp needlepoint drills are now considered the first choice for initiating osteotomies for all types of implants. The needlepoint drill is used like a center punch creating precise osteotomies without slippage. They are indispensable for correcting angle position for implants in fresh extraction sites.



10

**X.**

Singular Copings, with buccal-lingual tabs and cross-bars, must be fully seated in the implant slots. Metal reinforcing bars are inserted into the suspension tabs in a straight-line manner without forcing the bar to the bottom of each tab.

The components with firmly adapted self-curing resin, create a strong metal/resin laminated foundation for fixed bridges and new or retrofitted removable dentures.

**Note:**  
*The Monorail System Singular Copings and reinforcing bars assembled in accordance with Dentatus printed instructions create a well-fitting splint and will not require any adjustments.*



19



Monorail Singular Coping

**Section A**

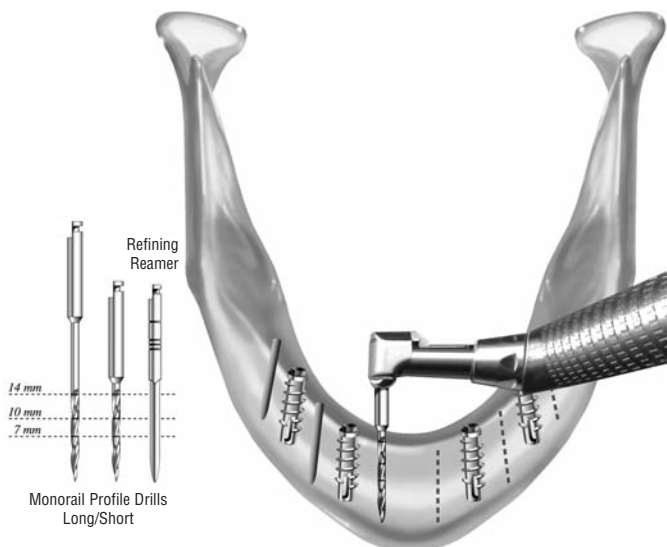
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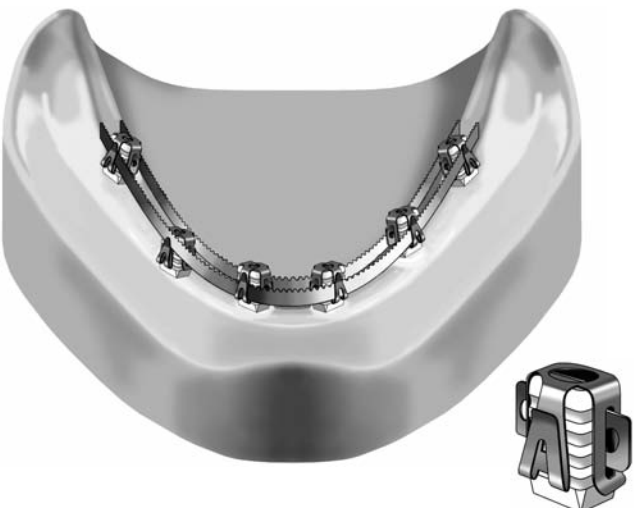
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Monorail Singular Coping

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The Monorail brass analogs inserted into the impression's firmly indexed copings, are carefully sealed for making the master cast. The master cast analog position must-not be altered or changed.

The Protective Spacers are placed over the exposed slimmer necks to fit under the square head of the implant. The spacers are reduced with fine scissors for bounce-free complete seatings of the modular coping cross-bar in the analog slots.

**Notes:**  
Conventional intra-oral registration markings and articulating procedures are followed in a routine manner.

When making splints, bridges, or relines, Protective Spacers must be used to prevent soft-resin from entering inside the copings that could cause distortions and/or interlock the restoration.



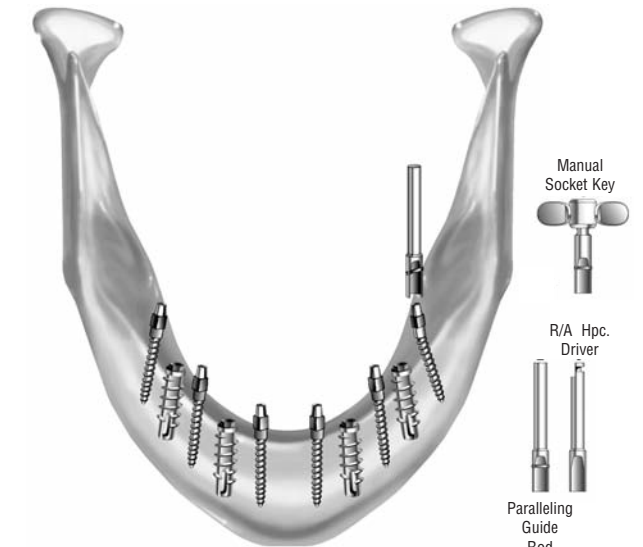
18

II.

The Monorail R/A Driver is used for initial implant placement to an intermediate depth of 3-5 mm. The installation is completed with the manual Socket Key with the cross-bar for visually aligning the implant slots with the crest of the ridge.

Monorail component design tolerate considerable mesio-distal, buccal-lingual divergent angles. Gross inter-arch implant misalignments can be corrected with the judicious use of the Paralleling Guide bending rod.

The Paralleling rod, with the cross-bar bisecting the implant slot, prevents its distortion or implant damage.



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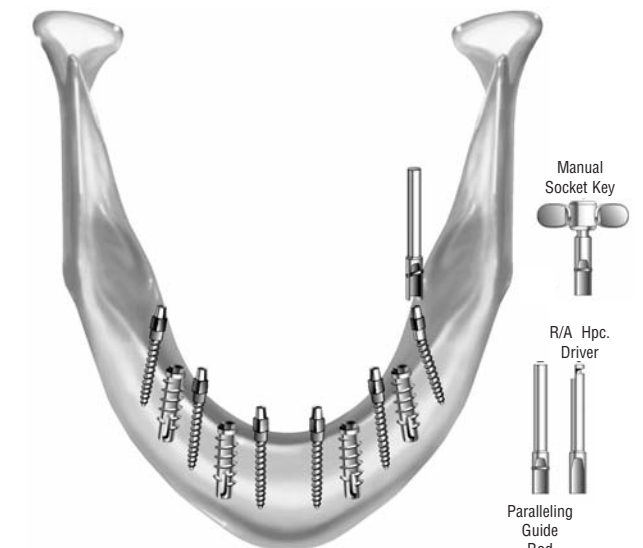
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To prevent polymerized resin from interlocking the assembly, Protective Spacers are placed over the slimmer implant necks under the square-head. The spacers can be reduced with fine scissors to permit complete bounce-free seating of the Singular Coping cross-bar in the implant slot.

**Notes:**  
To prevent soft resin tissue contact and suture entanglement, a 1/2" wide thin surgical paper tape is adapted over the implant heads in a buccal/lingual direction over the ridge before placing the Protective Spacers.



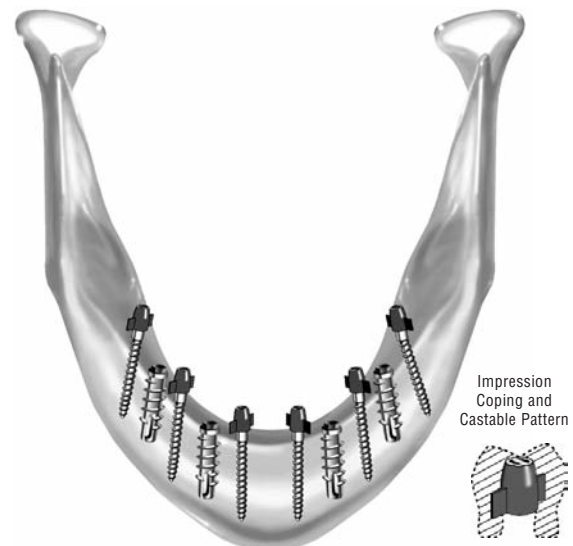
12

SECTION B.  
Monorail Prosthetic Technical Procedures

VIII.

Heavy-body elastic material is used to index and firmly hold the copings in the impression. The copings must be fully seated and the impression material is carefully injected around the copings for holding them firmly in place during the making of a Master Cast.

**Note:**  
Protective Spacers are not used for taking the impression. The Monorail Impression Copings can be cast in all types of precious and non-precious metals.



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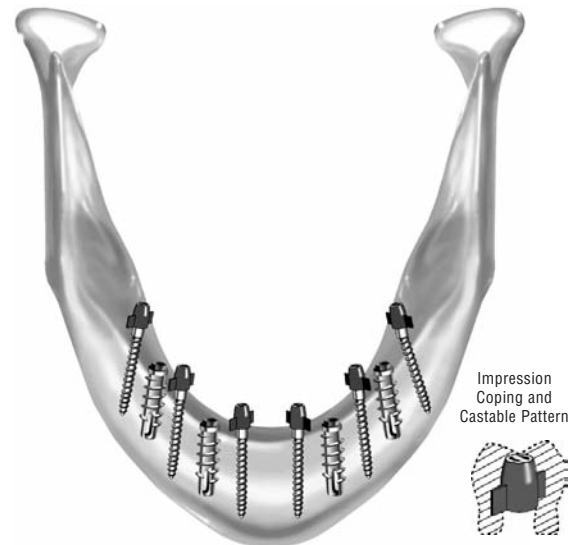
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17



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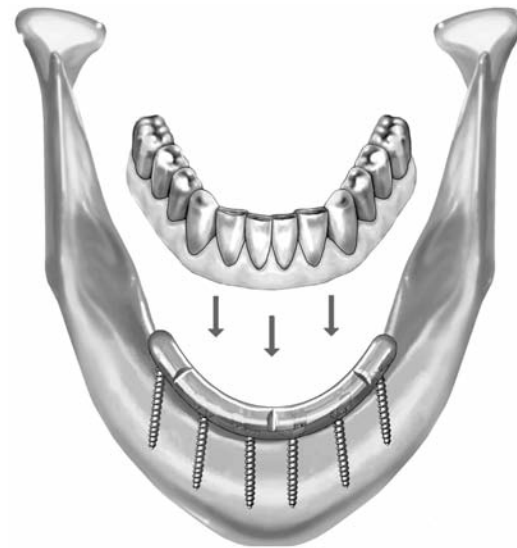
Chairside Splint Stabilization of implants and retrofitting existing and new removable dentures.

1. Monorail Implants are strategically installed through the mucosa into the bone to support the low profile splint.
2. The splint is prepared to a gentle ovoid-form with indexing grooves for the denture. The splint is smoothly finished and firmly cemented in place. Functional or new dentures are relieved to fit over the splint with additional space for soft-reline materials.

Excessive frictional retention can be corrected by reducing the reline interface contact for stress-free insertion and removal of the denture.  
See pages 22-23

### **Note:**

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



16

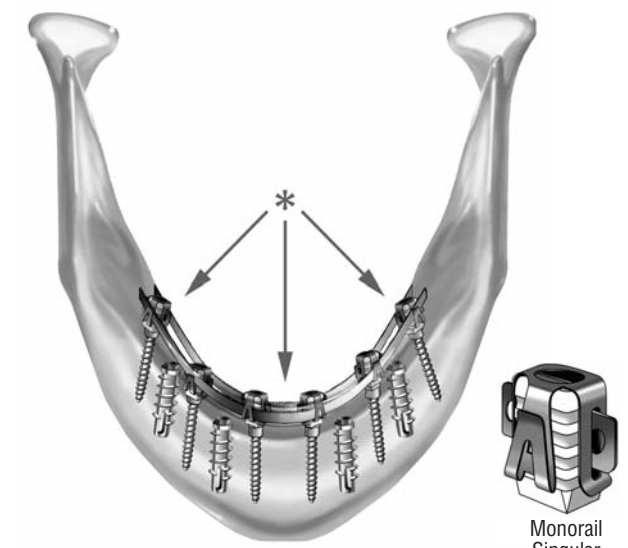
## IV.

Singular Copings, with buccal-lingual suspension tabs, are installed over the implants. Ti metal bars passively inserted into the tabs in a straight-line manner do not need to be forced to the bottom of each tab.

To prevent accidental patient's tongue-movement dislocation of components, small dabs of soft self-curing resin is selectively placed\* over the implant/coping bar assembly and allowed to fully polymerize.

Self-curing resin, placed into the Flexible Splint-Form, is allowed to reach a mildly tacky state for compressive seating and complete resin adaptation over the prosthetic assembly and ridge.

The splint should not be rocked or removed before the resin has fully polymerized to a rigid form.



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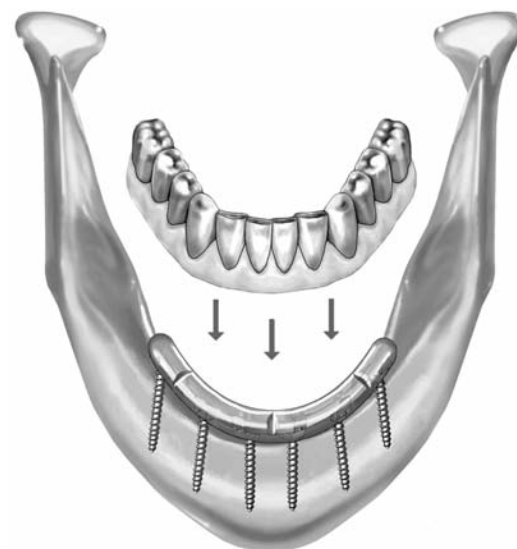
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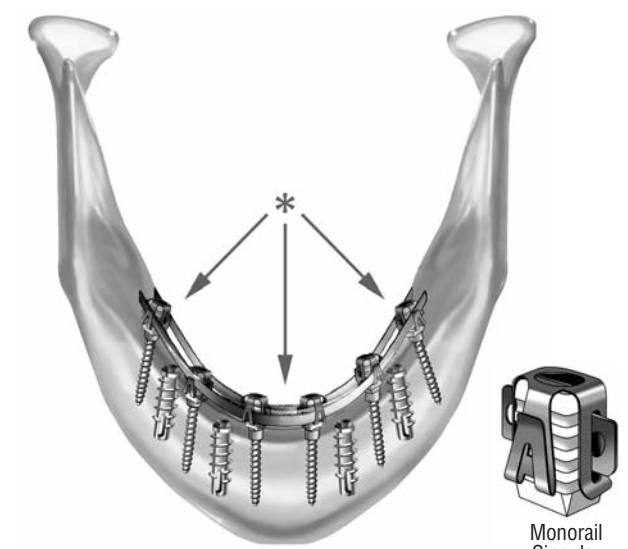
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V.  
The Monorail co-axial resin/metal splinted foundation made in accordance with the Dentatus printed instructions, should not require any corrections or adjustments. The resin/metal splint will not shrink or deform and may be used for strong dependable support of restorations.

**Note:**  
Protective Spacers must be placed over the implants slimmer necks under the square head in all procedures, such as making relines, attaching dentate forms to the splint, or correcting tissue contact deficiencies.

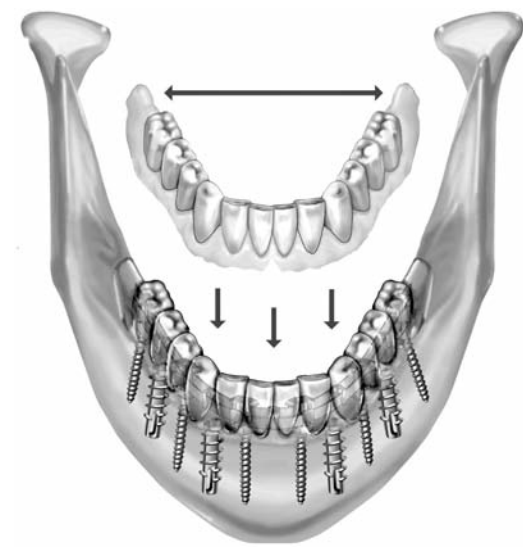


VI.  
Chairside restorations can be made with the use of vacuum-formed dentate replicas extended over the stable retromolar pads or tuberosities as seating stops. The replica, filled with soft consistency tooth-color resin, is aligned and compressively placed over the splint to affect a firmly attached prosthesis.

The alternate method is to use a wider shell-type laboratory pre-fabricated bridge. It is carefully aligned and attached to the splint with tooth-color self-curing resin.

The restoration is refined to ideal form and balanced occlusion before it is firmly attached with hard cement over the implant.

**Note:**  
When making splints, bridges, and relines, the Protective Spacers must be used to prevent soft-resin from entering the copings that can cause distortions and interlock the restoration.  
See instructions for laboratory techniques in Section B.



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