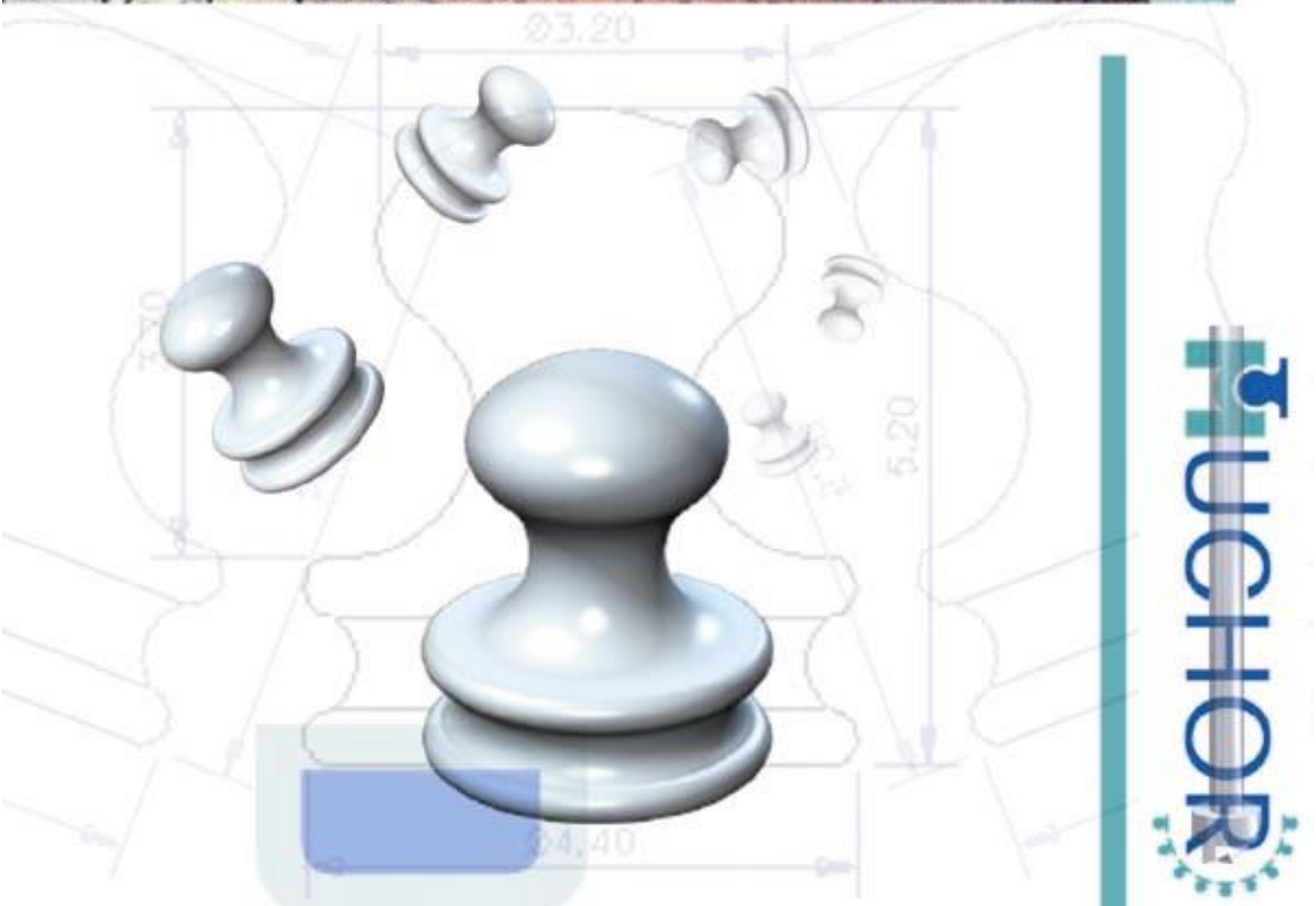
MANUAL

Dyna Muchor



MUCHOR

by Robert K. Biesaga DDS

Fabio Gonçalves MS, DDS

DYNA

General Information

Dyna Dental Engineering BV, Bergen op Zoom the Netherlands has implemented and maintains a quality management system for the following field of activities: development, manufacturer and sale of dental implants and medical devices for dental restorations which fulfills the requirements of the following standards: NEN-EN-ISO 9001:2000 and NEN-EN-ISO 13485:2003.

Warning
The descriptions given in this enclosure are insufficient to allow immediate use of the Dyna Muchor® Mucosal Anchorage System. Guidance in the handling of the Dyna Muchor® Mucosal Anchorage System by an experienced operator is strongly recommended. Dyna Muchor® Mucosal Anchorage Systems must only be used by properly trained dentists/doctors and in combination with original components. For more detailed information please refer to the Dyna Muchor Manual as well as Dyna Terms of Guarantee – available on request.
With the publication of this instructions for use all previous are no longer valid.

Content package
See label on packaging

Precautions
Do not use when the packaging is damaged.
Denture without balanced occlusion and articulation will contribute to failure.
Improper technique can contribute to failure.
Use only in combination with original instruments.Dyna Muchor® anchors may not be altered in any way.

Side effects
Following complications may occur after insertion:
Inflammation, bone loss, swelling, pain, patient discomfort, tissue degeneration, mucosites, denture mobility.

Please note:
It is the user of Dyna products who is obliged to determine whether or not any products are suitable for a particular clinical situation. It is the user of Dyna products who is obliged to document in appropriate manner the products used for each patient. Dyna Dental Engineering BV disclaims any liability, express or implied and shall not be responsible for any damages arising from or in connection with any errors in professional judgement or practice in the use or installation of Dyna products. It is the users duty to study the latest developments in dental implantology as well as Dyna Implant Systems and its applications. When using our product intra-orally take proper care to prevent them from being inhaled or ingested.

Handling and Storage
Handle with care.
Store in clean, dry, dust-free, dark room at room temperature.

Delivery
Federal law restricts these devices to sale by or on the order of a dentist or a physician.

Traceability of serial/lot numbers
It is the end users responsibility by law to record the serial and/or lot numbers of all products for traceability purposes.

Training
Dyna Dental Engineering BV arranges regular training courses for the beginning and advanced dental professionals. The courses are obligatory and are meant to provide the Dyna user with practical and theoretical expertise concerning the use of Dyna Muchor® Mucosal Anchorage System.

Copyright and trademarks

Explanation Symbols

REF	Catalogue number, article code
SN	Serial number
LOT	Batch code
	Manufacturer
	Attention, read instructions for use
	Single use only – do not reuse

CE 0344
Product complies with MDD 93/42/EEC

KEMA CERTIFICATE
ISO 9001:2000
ISO 13485:2003
DUTCH COUNCIL FOR ACCREDITATION C 013

Manufactured by:
Dyna Dental Engineering B.V.
Korenbeurstraat 26
4611 PW Bergen op Zoom
The Netherlands
Tel.+31 164258980
Fax.+31 164 258390
E-mail: dyna@dynadental.com
www.dynadental.com

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Table of Contents

contents

1. Introduction

The use of dental implants has become a scientifically accepted treatment concept to replace missing elements of the dental arch. The range of possible implant applications is wide and gives the clinician a chance to plan full rehabilitation of the mouth. The use of implants in combination with different barrier membranes has undoubtedly changed dentistry in the past few years but, due to the uncertain outcome, many clinicians are still not sure of their use. Also, not every patient is willing to undergo such extensive treatment. Various limitations made us look for other possible solutions that could be used for retaining dentures in the mouth.

This manual presents an alternative technique to simply provide the patient wearing partial or full upper dentures with better retention and stabilisation. It presents basic information concerning surgical and prosthetic procedures accompanied by practical tips for both the dentist and the dental technician.

We can imagine that some questions may be left unanswered after reading this manual. For this reason, and in view of the extremely fast changes in dental market, we recommend attending lectures, and reading the available scientific publications appearing in dental magazines and books. To acquire, on the other hand, indispensable practical skills we strongly advise attending one of the courses, given by experienced specialists keen to share their knowledge with you, organized by Dyna Dental Engineering BV.

In case of any questions you can always visit our website **www.dynadental.com** or contact us directly on the telephone number +31 164 258980 Fax +31 164 258390 E-mail dyna@dynadental.com.

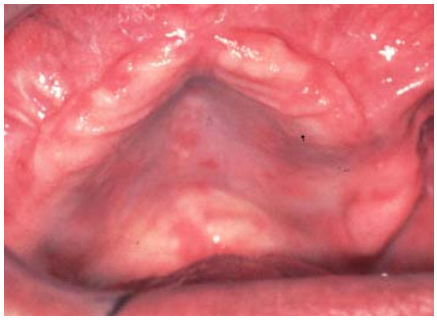
1.1 Indication & Contra indications Muchor®

Muchor® can be defined as an attachment-like retention system designed to be fixed to the denture to increase its retention and stabilization. It consists of ceramic elements (Ytrium stabilized zirconium oxide), more or less elliptical in cross section, that act as intra-mucosal anchors.

INDICATIONS

Its primary indication is to achieve retention and stabilisation for an upper denture. Especially Muchor® mucosal anchors can also be indicated for patients normally using a denture adhesive. Muchor® mucosal anchors can additionally be an option in those situations where implant indications are limited and/or financially not possible. Due to its simplicity and efficiency there are many diverse indications (for the Maxilla):

- implant contra-indications
- cleft palate
- vestibule that can not be operated
- atrophic upper jaw
- hyper gag reflex patients
- epitheses constructions



CONTRA INDICATIONS

All contraindications associated with elective oral surgery should be noticed. The scope for the use of Muchor® depends on the particular clinical case and can be modified or adjusted to the individual patient's situation. It is therefore important to judge every case thoroughly and take into consideration the following contraindications:

- **denture without balanced occlusion and articulation**
- mucosa thickness less than 2 mm
- haemophilia
- flabby ridge
- diabetes mellitus
- lack of motivation to perform adequate hygiene
- acute or chronic leukaemia
- patients using anti coagulants
- limitation deriving from anatomy of the jaw
- severe hypertension
- very recent myocardial
- HIV virus
- infractions

Most of the contraindications stated above must be considered conditional and temporary rather than absolute.

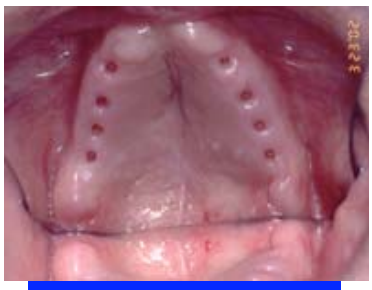
In most cases, it is the severity of the condition and the patient's residual ability to tolerate treatments that determine whether or not any therapy is contraindicated. In addition, there are a number of systemic medical conditions that can cause complications during the healing stage, and may contribute to treatment failure. These factors must also be assessed by the operator.

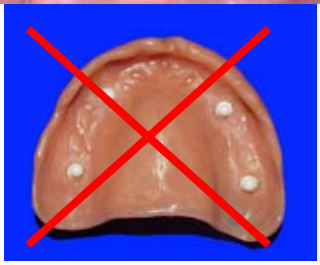
1.2 Why use Muchor®?

In some situations the application of conventional prosthetic restorations is limited. This can be related to medical, clinical and/or financial limitations, fear for treatment, or a combination of these factors. Therefore, there is a constant need to offer the dentists and their patients a system that is a simple and predictable solution to retention problems.

It is well known that most of the patients experience little or no problems with the function of their upper dentures. This fact, combined with the simplicity of the treatment itself, makes dentists offer this particular solution routinely. Minor complaints of patients are compensated by other factors such as price and patient acceptance. However, this does not mean that they have no wishes concerning their prostheses. It is striking how many patients ask about implants even though they can function well with their dentures. Most of them, if asked whether they would like to have the same denture but without a palate, would give a positive answer. This could also be extended to questions about retention and stability, chewing efficiency, comfort, or aesthetics. Such small changes made in a simple and inexpensive manner would certainly please all patients wearing dentures.

Muchor® is such a system. It is easy, economic and predictable; it gives a clinician the possibility to offer his patients an acceptable solution when extra retention and stabilization is needed.
The treatment is safe as it is reversible. If the treatment is not satisfactory to the patient for what ever reason, the anchors can easily be removed. The sites in the mucosa will be closed within a few days to a few weeks.





Minimally use 8 Muchor® anchors in the dorsal area. In very small maxilla 6 Muchor® anchors can be indicated to prevent placement in the front area.

1.3 History and scientific background

The idea of intramucosal inserts ("Muchor®") is not new in dentistry. The first reports came from Dahl and Nordgren from 1942 [1] ,who described a technique of forcing the inserts into the mucosa and fixing them into the prosthesis. Nordgren reported 30 cases successfully functioning for a period of up to 10 years[2]. This technique, though effective, was complicated and uncomfortable.

In 1953 Lew and Kersenbaum described a modified technique for "an implant button" for edentulous patients. It was based on the fixing of metal male parts into the prosthesis and, after transferring the position to the mouth and cross incising of the mucosa, inserting and pressing the prosthesis into place[2]. They noted, however, the necessity to adjust the size of the inserts as well as the appropriate technique.

In 1958 Cranin and Cranin proposed a technique using two different sizes of elliptical in cross section inserts of 2.0mm and 2.5mm made out of "non reactive metal". They were first determining the proper position for the inserts in the mouth and then transferring it into prosthesis. The technique allowed for using a trephine drill to create space in the mucosa and, if necessary, deepening the trephined receptor site by entering the cortical plate of bone with round drill.[3]

In 1961 the same authors described a modified technique using adjusted instruments and inserts. They also proposed other uses of the inserts (partial maxillary dentures, enabling clasp-less partial dentures, intermaxillary elastic hook in orthodontics or fractured dentures).[12]

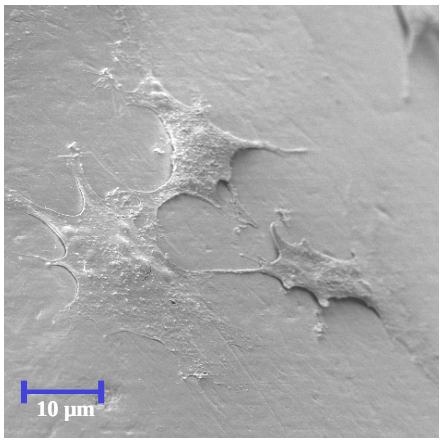
Dhal in 1966 stated "…intramucosal inserts based on clinical use during more than 25 years offer a reliable retention for upper dentures…"

In 1973 Weiss and Judy introduced a newly designed mucosal insert that proved more satisfactory because of the precision design of the insertion burs and insert, and the refinement of their placement into the prosthesis.[4] Babbush in 1976 wrote " modification of design and fabrication of precision insertion instruments for mucosal inserts have made this a useful procedure for patients with denture retention problems"

In 1982 Misch described the inserts as "mushroom shaped projections which are attached to the tissue bearing surface of a maxillary removable denture prosthesis". He stressed the role of the inserts in preventing the need of regular relining of the dentures, and the fact that there has never been reported evidence of dysplastic changes in the epithelium around an intramucosal insert. The technique described used modified metal inserts as well as two tissue drills.

1.4 Technical & Biological information

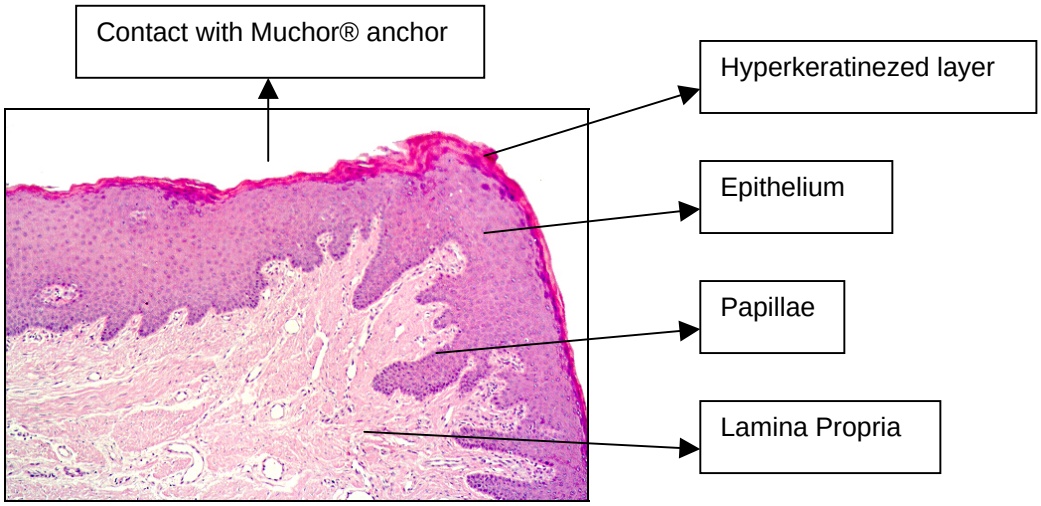
The Muchor® anchors are made out of zirconium oxide (ZrO_2,Y_2O_3 Ytrium stabilized). This material is well known for its outstanding mechanical properties for use in implantology. It is highly biocompatible, extremely hard and resistant to scratching[18, 19, 20, 21, 22]. Because of the fact that Zirconium oxide ceramics can be polished like glass or porcelain, the bacteria and plaque formation on its surface is significantly minimized. The shape of the anchors has been designed so that the mucosa could easily adapt itself around the Muchor® anchors. In this way the living tissue would act like a matrix for a ball attachment.



Cell growth on the Muchor® zirconium oxide anchors
SEM magnification 1000 x

Histology

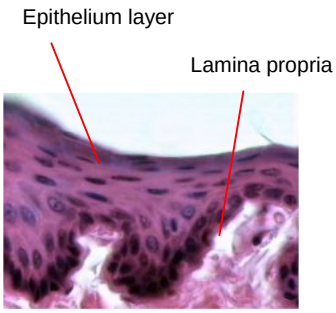
Histological findings by observing biopsies of the oral mucosa around Muchor® anchors did not change by comparing cuts done after 6 months, 2 and 3 years of denture use.



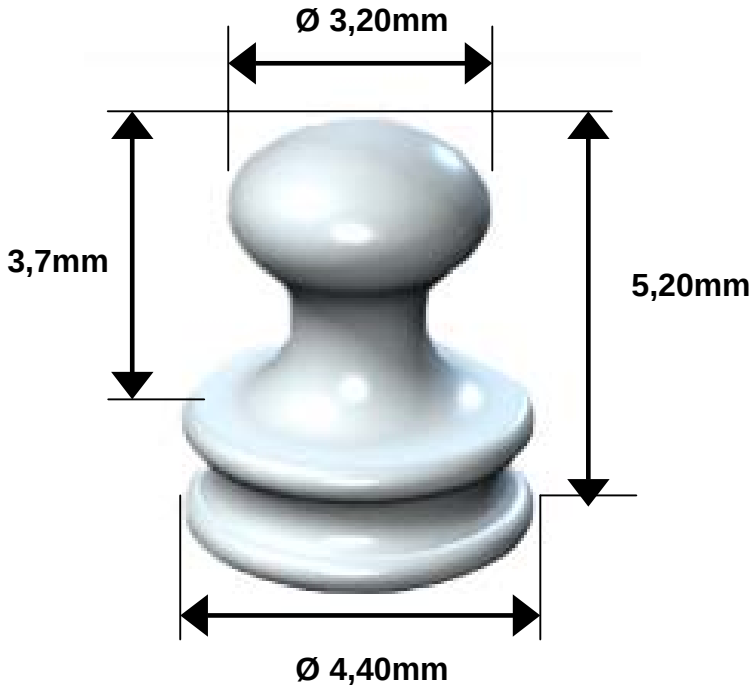
The histological picture shows the cronic response of long period, probably due to the loading and stress distributed on the epithelium. In this case the epithelium presented the increase of parakeratinization, hyperplasia (epithelium layers became thicker), and acanthosis (flatten epithelium crests). The described acanthosis and hyperkeratinezed layer are common findings in the mucosa of denture users.

Regarding the histological findings the following summery of the results can be given:

1- Oral mucosa : Observe epithelium and lamina propria
2- Epithelium covers the connective tissue in contact with the Muchor® anchors
3- No change was found in the epithelium in contact with Muchor® anchors
4- Presence of hyperkeratinized layer produced by the epithelium cells facing a chronic irritation (epithelium protection) which is a common finding under normal dentures
5- Acanthosis: epithelium layer becomes thicker
6- No evidence of dysplasia concerning the Muchor® anchors procedures, related in the international literature



Measurements of the Muchor® anchor.



1.5 References & Literature

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21 Lee JC et al Gut “Absence of skin sensitivity to oxides of aluminium, silicone, titanium or zirconium in patients with Crohn’s disease” 1996 Aug;39(2):231-3

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2. Product catalogue.

Muchor® anchors

Muchor® anchor 8pcs **91MA8**

Muchor® drills

Muchor® laboratory drill **91ML1**

Muchor® dentist drill **91MD1**

Muchor® sets

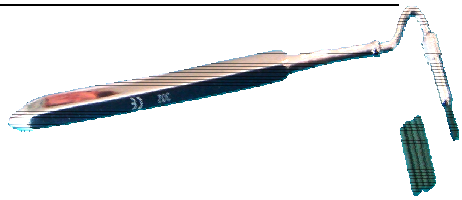
The Muchor® system set will be delivered in one package including:
8 Muchor® anchors
1 Muchor® dentist drill Ø 3,7mm
1 Muchor® laboratory drill Ø 4,7mm

Muchor® set complete incl. drills **91MS1**

Muchor® auxiliaries

Muchor® Marker Holder **92EL1**

Muchor® Marker Tips (8pcs) **92LT8**



3. Clinic

3.1 General information

The use of Muchor® system will be shown using simple examples of basic indications for this type of Anchorage system.

Muchor® is mainly indicated for improving retention and stabilization of full upper dentures. The idea of its function is based on the natural healing process of the mucosa.

The technical procedure for making a denture with Muchor® anchors resembles that of a full denture, which makes it suitable for all practitioners. Nevertheless, every case should be treated with adequate care and responsibility. Careful examination and detailed planning is necessary to avoid any disappointments. Attention should be paid to the contraindications (see page 5) and if necessary patient should be adequately prepared.

USING THE MUCHOR® SYSTEM IT IS OF PRIMAIRY IMPORTANCE TO PRODUCE DENTURES WITH A BALANCED OCCLUSION AND ARTICULATION

Muchor® anchors can be fixed either in a new or in an already existing denture. This procedure can be combined with a rebase procedure or performed by the dentist chair-side. The chair-side procedure is faster and saves time for the patient, whereas, all lab-involved methods increase the precision and durability of the work.

Using the Muchor® system can be divided into four steps:

Step one	-	Production of the denture
Step two	-	Fixing the 8 Muchor® anchors into the denture base
Step three	-	Preparation of the Muchor® sites, in the mucosa
Step four	-	Healing

3.2 Clinical procedure

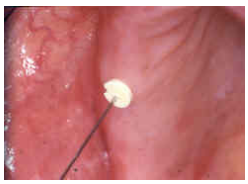
The example below shows the application of the Muchor® system in an existing full upper denture with a balanced occlusion and articulation with retention problems.

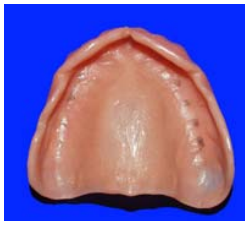
In the case of producing a new denture, the normal procedures for a full denture case should follow first. A wear-in period to detect any problems with the denture is a must. Only after solving them can the Muchor® system be used.

First appointment

This appointment is intended to gather all the necessary medical data needed to proceed with the desired treatment, and give the patient all the information about the denture- its advantages, time-planning etc.. The following factors should be taken into consideration:

- Medical status
- Analysing of the existing prosthetic restoration. Occlusion, articulation and retention should be noticed
- Analysing X-ray photos
- Intraoral inspection (measurement of the mucosa thickness)
- Planning. Any additional treatment should be planned and discussed with the patient





DENTIST

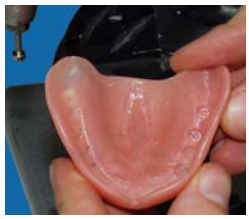
Measure the mucosa thickness. Search the mucosa areas with a thickness of minimal 2,5mm. The ideal thickness of the mucosa is approximately 3,75mm. *Drilling into the bone to provide sufficient space for the Muchor® anchor is possible. There must be around 1mm space on top of the anchor. Consequently a X-ray examination (OPG) is a must (anatomy).*

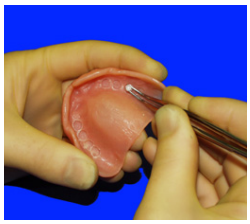
The measurements may be taken ultrasonically or with a sharp injection needle with an endodontic stop. (This technique resembles bonemapping in implant surgery procedures)
Mark the ideal 8 Muchor® anchor positions with the Muchor® Marker on the acrylic of the denture.

LABORATORY

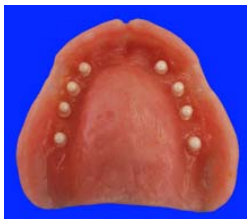
Prepare the sites for the fixation of the Muchor® anchors in the marked places with the Muchor® laboratory drill.
It is recommended that a surveyor is used in order to assure the proper path of insertion.

Verify the preparations and fix the anchors with e.g. self or light curing resin.



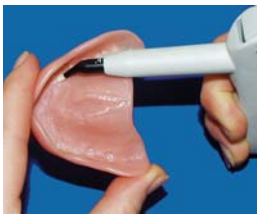


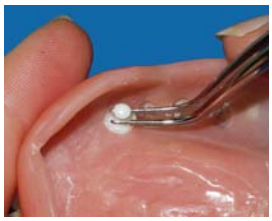
Remove the excess of the resin and polish the sites carefully with small polishing instruments.



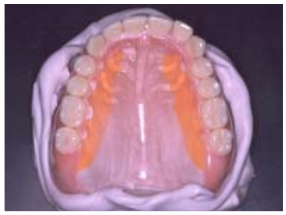
Please note:
Fixing the 8 Muchor® anchors can also be carried out as a chair-side procedure. However the laboratory method increases the precision and durability of the work.

Note: Insert the 8 Muchor® anchors as parallel as possible.



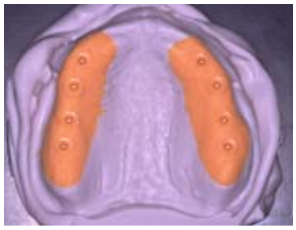


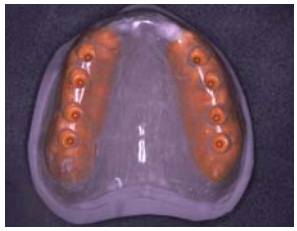
To assure a perfect position of the Muchor® anchors intraorally a drilling guide is required. *This drilling guide can be used later as a night guard. (see paragraph 3.3).*
Cover the head of the Muchor® anchors in the denture with putty material (e.g. Gingifast®) and make a putty or plaster model.



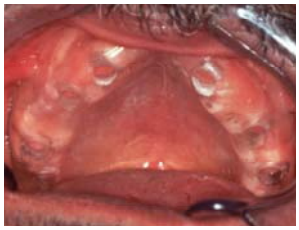
Put the model under the vacuum forming machine.
Heat the vacuum forming plate and draw the plate over the model.

Take off the plate and finish the outline.



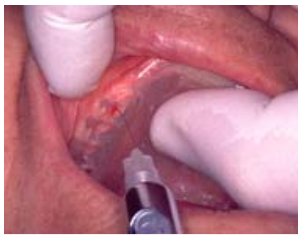


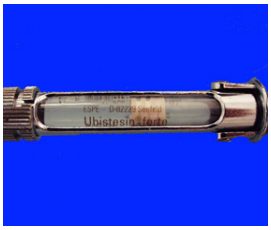
Second appointment



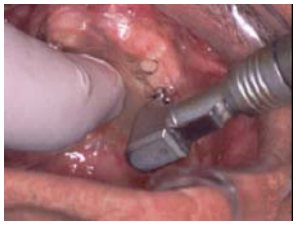
DENTIST

Place the drilling guide in the mouth and verify the fit.

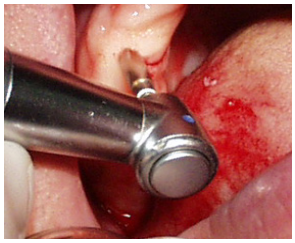


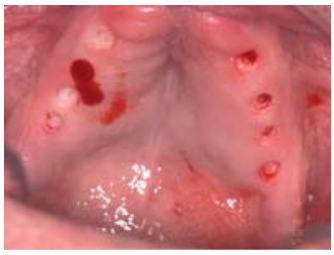


Anaesthetise the areas where the mucosa anchors are going to be placed.
One cartridge is more than enough to achieve adequate anaesthesia. Large quantities could disturb the denture insertion.



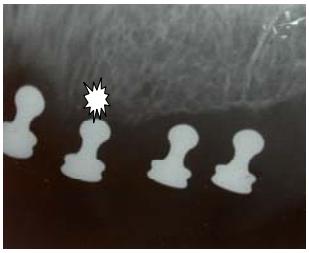
Use a diamond drill to make the initial preparation sites.

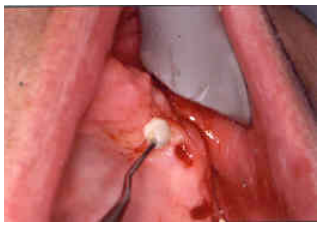




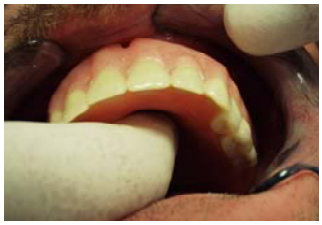
Make the final preparations with the Muchor® dentist drill. The length of the drill is equal to the depth of the preparation sight.

Please note:
Although the surgical procedure for the Muchor® system is very simple it should not be underestimated. Surgery should comply with all requirements for this type of procedures and all needed instruments be properly sterilized. **To prevent contact between the Muchor® anchors and the periostium one would be forced to drill into the bone provided that all anatomical aspects (e.g. sinus maxillaris) have been taken into consideration.**

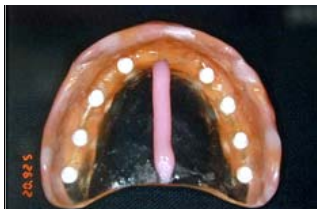


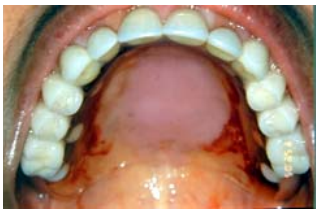


In case of doubt regarding the fit of the denture the preparations can be checked with a Muchor® anchor.

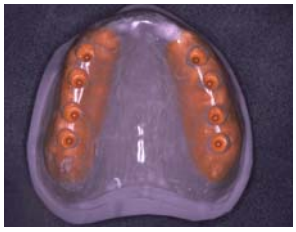


Insert the denture firmly; check the fit, the occlusion and articulation. Patient should not remove the denture for the first 72 hours. Inform the patient about the importance of keeping the denture in place and that smoking is not allowed during the healing period. Prescribe painkillers. Rinse with chlorhexidine twice a day.



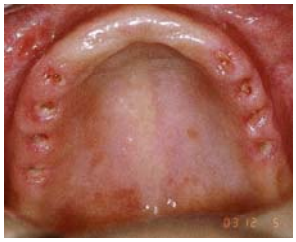


To increase the stability and retention during the healing period a dental adhesive should be used.

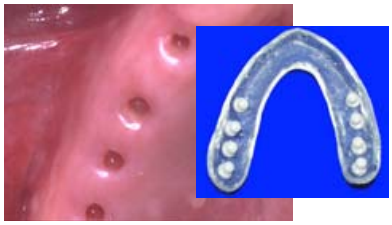


After the 72 hours of healing it is recommended to use a night guard during the night. Send the putty model with the drilling guide to the laboratory to change the drilling guide into a night guard. (See paragraph 3.3)

Third appointment



After 72 hours see the patient and take out the denture. Check the fit, remove the pressure points if necessary and give further instructions. We recommend seeing the patient again after three days and further appointments when necessary. Healing of the mucosa takes around two weeks in normal conditions.



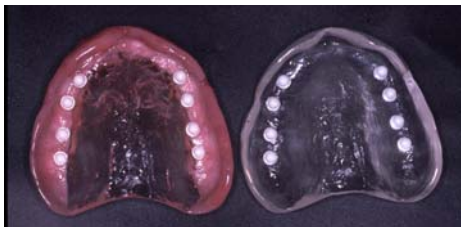
The denture should be in place day and night until complete healing has taken place, though the patient should take out the denture every day and clean it properly. At night the night guard can be used.

Special gels containing pain-killer and Chlorhexidine (e.g. corsodylgel 9,0 with 2% xylocain) may be applied in and around anchors before reinserting the denture. Instillagel® is a brand which could be used. The patient should also use chlorhexidine mouth washes. If needed additional pain killers may be prescribed. No antibiotics are necessary unless there is severe infection.

THE DENTURE CAN ONLY BE TAKEN OUT FOR CLEANING.

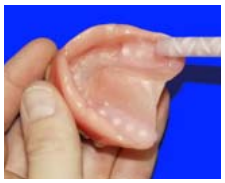
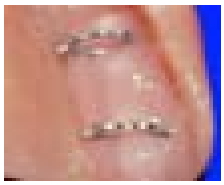
3.3 Night guard

A “night guard” is recommended. The night guard is a sort of thin plate with reduced palate provided with Muchor® anchors in positions that correspond to the ones in the denture. It is designed to be worn at night or in cases when the patient can not wear the prosthesis as a result of e.g. *mucositis* or when the denture is under repair.

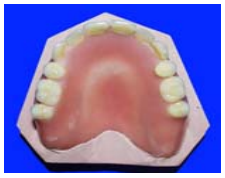


Technical procedure when no drilling guide was used:
The procedure described below is only an example of the technique showing the general idea of the production of a night guard. Our goal is to present technical details to help the technician as much as possible.

Cover the head of the Muchor® anchors with a putty material (e.g. Gingifast®). By placing some metal anchors in the elastic material before hardening, you will enhance the connection to the putty.

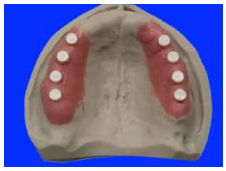
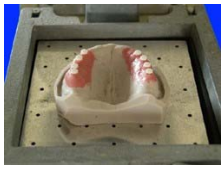



1. Make a putty model of the denture




3. Separate the putty model

4. Place new Muchor® anchors into the Gingifast® parts of the putty model

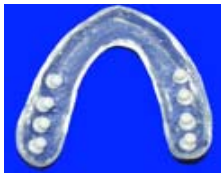



5. Put the model into the vacuum forming machine

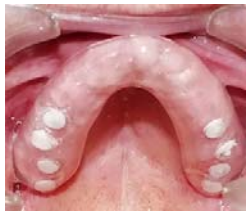
6. Heat the vacuum forming plate and draw the plate down over the model


7. Take off the plate and finish the perifery

8. Put the anchors back in the model; make little holes in the plate at the position of the anchors and fix with self curing resin

9. Let the acrylic cure; remove the excess of the acrylic



10. Polish and finish the night guard and send it to the dentist

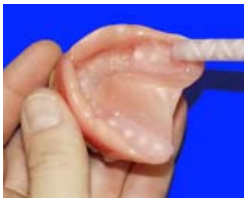
3.4 Rebase procedure

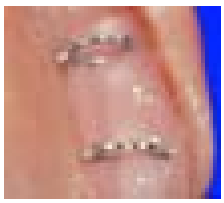
Judy and Weiss have published in the Journal of Oral Implantology that intramucosal inserts conserve edentulous ridges and increase retention and stability of removable maxillary prostheses[5]. During the 5 year clinical evaluation Muchor® mucosal anchors no rebase procedures were indicated.
However in the event a rebase procedure is indicated, the following procedure can be used.

DENTIST
Make an impression as usual with the Muchor® anchors in place. Inject the impression material (light body) around the anchors, take the impression and send it to the laboratory.

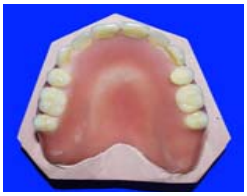
NOTE: If the Muchor® anchors are fully covered by a layer of impression material it can mean that the sights in the mucosa are too large. In this case the total clinical and laboratory procedure must be done again.
Remove the Muchor® anchors from the denture and fill the holes with a cold cure resin and give the denture to the patient. After two weeks make the rebase impression and send it to the laboratory. The laboratory can now start the procedure as described in the manual.

Cover the head of the Muchor® anchors with hard body silicone material. By placing some metal anchors in the elastic material before hardening you will enhance the connection to the plaster. Than pour out in stone and proceed with normal hot cure or cold cure rebase procedure.

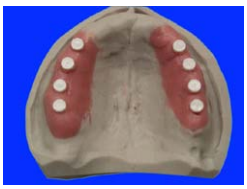


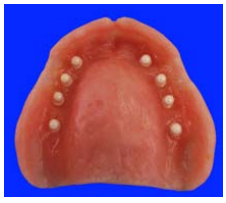


After removing the denture from the model the Muchor® anchors are removed from the denture. This can be done easily by heating the acrylic (gradually!) around the anchors. Remove heated acrylic and prepare the denture as normal.



Replace the Muchor® anchors in the model and proceed with the rebase procedure as normal. Finish the denture and send it to the dentist.





Dentist can now place the denture and check the occlusion and articulation! Check the denture after a week on pressure points, occlusion and articulation.

3.5 Instructions for the patient

After surgery:

- do not take out the denture for the first 72 hours after placement
- at night wear the night guard
- rinse the mouth with 1.5 % solution of chlorhexidine twice a day
- 72 hours after surgery the denture must be removed by the dentist and cleaned thoroughly
- during the healing period of approximately 15 days (after the 72 hours) take out the denture only for cleaning
- when indicated by the dentist use Instillagel® or xylocain gel with chlorhexidine during the healing period after the first healing period of 72 hours. This gel will give comfort to the patient when the denture is inserted. Apply the gel directly on the anchor sites in the mouth and wait for approximately 1 to 2 minutes.
- if the denture comes out put it back immediately
- use painkillers if necessary during the healing phase.

General:

- clean the denture twice a day (using special a denture brush and soap is sufficient)
- after complete healing do not remove the denture for longer than 1 hour
- after the healing period it is recommended to rinse with chlorhexidine once a week
- always contact your dentist in case of any suspicious changes of the mucosa.

4. Miscellaneous

4.1 Packaging & Labelling

How to open the packaging

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2.

3.

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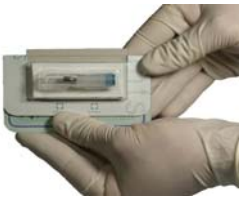

5.

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How to use labels for traceability purposes

1.

2.

GENERAL CONDITIONS OF SALE AND DELIVERY OF THE PRIVATE LIMITED LIABILITY COMPANY DYNA DENTAL ENGINEERING B.V., ESTABLISHED IN BERGEN OP ZOOM (NL) AT KORENBEURSSTRAAT 26, AND REGISTERED AT THE BREDA CHAMBER OF COMMERCE (1997)

Art I General

In these conditions of delivery the following definitions shall apply:

- product: goods as well as services,

In these conditions the following terms shall also be taken to mean:

the supplier: Dyna Dental Engineering BV. the buyer/customer: anyone, or any business, acting under whatever legal form, with which Dyna Dental Engineering B.V. had concluded a written agreement with regard to the delivery of goods and/or the provision of services.

- parties: supplier and buyer/customer
- service: the installation/assembly of products and the organisation of courses and presentations.

Art. II Offers

1. All agreements between the supplier and the buyer/customer are governed by these General Conditions unless and to the extent specifically agreed otherwise in writing and signed by both parties.
2. All suppliers' offers, in whatever form they are made, are without prejudice: the supplier is only bound after it has definitively accepted an order or confirmed a sale in writing; all agreements or promises which it may have made previously and which it has not accepted in writing shall be null and void.

Art III Agreement

1. If the agreement has been concluded in writing, it shall be formed on the day of signature of the contract by the parties.
2. A change in and/or addition to an agreement shall only be formed if it has been expressly accepted by the parties in writing.
3. Oral promises by and agreements with (subordinates of) the supplier shall not be binding on the supplier until and to the extent that they have been confirmed by it in writing.

Art. IV Price

1. The sale's price is calculated for deliveries ex-warehouse. The sale's price is based on the prices, exchange rates, wages, taxes, duties, costs, etc. which exist at the time of the confirmation. In the event that one or more is increased the supplier is entitled to change agreed prices accordingly, even if the increase takes place by virtue of circumstances which were already foreseeable at the time of the offer or acceptance or confirmation, all this under observance of the applicable statutory provisions. For deliveries amounting to less than a total amount of Euro 400.00 (in words: four hundred Euro) per order then not only the dispatch costs, but also any other costs, including handling costs, are charged.
2. Any installation work, and also the costs for any courses and accompaniment, are always for the account of the buyer, unless agreement to the contrary is made in writing.

Art. V Delivery time

1. The delivery time shall commence on the last of the following times:
   a. the day of formation of the agreement;
   b. the day of receipt by the supplier of the documents, details, permits etc. which are necessary for the performance of the agreement;
   c. the day that the formalities which are necessary for the commencement of the work have been fulfilled;
   d. the day of receipt by the supplier of what should have been paid in advance according to the agreement before the work was commenced.

   If a date or week of delivery has been agreed upon, the delivery time shall commence on the agreed date.
2. The delivery time is based on the work circumstances which apply at the time of the conclusion of the agreement and on a in time delivery of the materials ordered by the supplier for the performance of the work. If a delay arises outside of the fault of the supplier as a result of changes in the said circumstances or as a result of the fact that the materials necessary for the performance of the work which were ordered in time are not delivered in time, the delivery time shall be extended as far as is necessary.
3. The product shall, in terms of the delivery time, be considered to have been delivered if, in the event that a inspection in the business of the supplier has been agreed upon, it is ready for inspection, and in all other cases when it is ready for dispatch, all this after the customer has been notified thereof in writing and without prejudice to the obligation of the supplier to comply with any assembly/installation obligations which it may have.
4. Without prejudice to the provisions given elsewhere in these conditions with regard to an extension of the delivery time, the delivery time shall be extended by the duration of the delay which arises on the side of the supplier as a result of the non-compliance by the customer of any obligation arising under the agreement or cooperation which is to be demanded of it with regard to the performance of the agreement.
5. Except in the event of crass fault on the side of the supplier a transgression of the delivery time shall not give the customer any right to fully or partially dissolve the agreement. A transgression of the delivery time - as a result of any reason whatsoever - shall not give the customer the right to carry out work or have work carried out without a court authorization in order to implement the agreement.

   In the event of an excessive transgression of the delivery time, this, however, according to the assessment of the supplier, the latter shall enter into further consultations with the customer.

Art. VI Claims

Without prejudice to the provisions given below, the customer shall inspect the product as quickly as possible after delivery.

1. Claims based on immediately visible defects must be submitted in writing and by registered mail by the customer to the supplier within 10 (in words: ten) days after the delivery or after the services concerned have been carried out, failing which the right to make a claim based thereon shall have lapsed.

2 If and to the extent that the claim relates to the delivery of precious metals, a second delivery or an additional delivery shall be made at the prices for the product which apply at that time. The above shall not affect the right of the supplier to take back the precious metals which have been delivered in return for crediting the customer for the amount of the purchase price or - instead of an additional delivery - to credit these at the value of the goods which were not delivered.

Art. VII Payment

1. All payments must be made 14 days after delivery or, for goods which are destined to be delivered in an operational state by the supplier, or for services, before the date mentioned on the invoice.
2. All payments must be made at the office of the supplier, without deduction or compensation of debts, or on a bank or post office account which is to be indicated by the supplier.
3. If the customer does not pay within the term indicated by supplier, he is deemed to be automatically in default from the due date and the customer will pay, without any further notice one percent interest per month on the entire amount due starting from the due date, without prejudice to further rights which accrue to the supplier, and the customer will further reimburse all costs incurred for the recovery, including without limitation attorney's fees and court costs, as well as out-of-pocket expenses which are fixed at fifteen percent of the amount claimed excluding VAT which is due with a minimum of Euro 250.00 (in words: two hundred and fifty).
4. No payments may be suspended, even if the customer believes that it is entitled to make a claim.

Art. VIII Reservation of ownership

Until full and irrevocable payment has been made of all payments owed by the customer to the supplier the supplier reserves the ownership of all goods which it has delivered, this as security for the payment of everything to which it is entitled, nothing excepted, and including the after mentioned interest and recovery costs; the customer shall therefore, as long as no full payment of everything to which the supplier is entitled has been made, not be allowed to dispose of, lend, pledge or mortgage, nor let or lend out the goods which have been delivered to it or take same outside of its premises in any manner or under whatever title, unless customer is a professional trading firm, of which the sale of that which has been delivered is the aim, in which case it is entitled to make such sales in the normal course of business; in the event of breach of any of the provisions given here article 12 (in words: twelve) is applicable.

Art. IX Effort

1. In case products were delivered as part of deliveries under a distribution contract the buyer is obliged to make every effort to sell the products which have been supplied by the supplier as well as possible on the market on which the buyer operates. The buyer thereby undertakes to give as much publicity as possible with respect to the products delivered by the supplier, all this by means of presentation of the products at trade exhibitions, advertising the product in the professional magazines which are suitable therefore, recruiting to that end employees who are expert and well equipped in that respect, both in the internal and external sales teams.
2. The pure fact that a purchase quantum which has been agreed upon in advance with the supplier under such distribution contract is reached does not in itself discharge the buyer from the above mentioned obligations. The supplier reserves the right to early terminate any such contract and other agreement which has been concluded with the buyer if the buyer, after reasonable learning, remains in default with regard to the obligations mentioned above.

Art. X Liability

1. Except for the guarantee obligation described in article 11 (in words: eleven) the supplier is not liable for damages as a result of whatever cause on the side of the customer or third parties in connection with goods delivered or services provided by the supplier, delivery obligations, the delivery of goods or the use thereof unless and to the extent the sole and direct cause of such damages is held to be wilful misconduct and gross negligence by supplier. Wilful misconduct and gross negligence by supplier's personnel and third parties which the supplier uses does not therefore lead to liability of supplier.

   The buyer shall indemnify the supplier in respect of all costs, damages and interests which might arise out of any connection with claims by third parties due to any defect in or by virtue of products which have been delivered.
2. The supplier is therefore also not liable for:
   - infringement of patents, licences or other rights of third parties as a result of use of details provided by or on behalf of the customer;
   - damages or loss which have arisen through normal use of raw materials, semi-finished products, models, tools and other goods which have been made available by the customer.
3. If the supplier provides help and support with the assembly, although it has not been contracted to carry out the assembly, then this will take place for the risk of the customer.

Art. XI Guarantee

1. The supplier guarantees the buyer that its own products or products which it has manufactured itself are fit for the application which it has indicated or which appears from the agreement, in the sense that, if the product turns out to be unfit, the supplier shall, as it elects, replace the product without charge or repay the purchase price in return for the return of the goods if these have not been processed, all this without prejudice to article 6 (in words: six).
2. In any event the guarantee shall not include defects which occur 3 months after the delivery and which are entirely or partially the result of:
   a. non-observance of user and maintenance instructions or use other than the normal use which was foreseen, such as, but not limited to, the exposure of the goods to abnormal circumstances such as contamination;
   b. normal wear;
   c. assembly/installation or repair by third parties, including the customer;
   d. the application of any government regulation relating to the nature or quality of the applied materials;
   e. materials or goods which have been applied or used in consultation with the customer;
   f. materials or goods which have been provided by the customer to the supplier for processing;
   g. materials, goods, methods and constructions, to the extent that they have been applied on the express instructions of the customer, as well as materials and goods supplied by or on behalf of the customer.
   h. the storage of the product for longer than usual, and it is plausible that as a result of this a loss of quality has occurred.
3. If the supplier delivers new products or parts, or provides new services in order to comply with its guarantee obligations, then all of the provisions of these conditions shall be applicable to these products, parts or services.
4. Non-fulfilment by the customer of any of its obligations, such as those regarding payment, releases the supplier from its obligations referred to in this article, and also from all other obligations hereunder. Fulfilment of its guarantee obligations by the supplier shall be deemed sole and full compensation of damages.

   The customer is not entitled to make any other claim for compensation of any damages whatsoever, or to sue for dissolution of the agreement.
5. The alleged non-compliance by the supplier with its guarantee obligations shall not release the customer from the obligations which arise for it under any agreement concluded with the supplier.
6. Claims in respect of defects must be made in writing as quickly as possible after they are discovered, but at the latest within 14 days after the end of the guarantee term, and if this term is transgressed all claims against the supplier in respect of those defects shall lapse. The customer is obliged to give the supplier the opportunity to investigate the defect which has been discovered as quickly as possible. Legal claims relating to guarantee must be brought within one year after the in time claim on pain of their lapsing.
7. Unless agreement to the contrary has been made, in respect of repair or revision work carried out by the supplier or other services guarantee shall only be given on the soundness of the performance of the work which was instructed, this for a period of 6 months. This guarantee shall only entail the obligation of the supplier to carry out the work again in the event of unsoundness of the work concerned. Section 3 of this article shall be likewise applicable in that event.

No guarantee shall be given in respect of the inspections, advice and similar activities carried out by the supplier.

9. All goods sold by the supplier must be used and processed in accordance with its instructions and/or the user instructions given on the packaging and in the manuals.

Art. XII Dissolution

If the customer does not comply with any obligation which might arise from this agreement or any other agreement concluded with the supplier, or does not comply therewith in time and properly, and also in the event of bankruptcy, moratorium of payments, operational close-down or liquidation of the business of the customer, it shall be deemed to be automatically in default and the supplier shall have the right, without any further notice and without court intervention, to suspend performance of its obligations under the agreement or to dissolve the agreement in whole or in part, as it elects, without it being obliged to pay any compensation of damages or to provide any guarantee, but without prejudice to the further rights which accrue to it. In these cases all claims which the supplier has or shall acquire on the buyer, such as for payment and suply back of goods in possession of the buyer under retention of title, shall become immediately due and payable in full.

Art. XIV Disputes All disputes, including those disputes which are only considered to be such by one of the parties, which might arise between supplier and customer raising out of or in connection with an agreement, further agreements and/or the (non-) performance of obligations there under, concluded between the supplier and a customer, shall be judged in first and last place by the ordinary court in the place of establishment or the court district of the supplier.

Art. XIII Applicable law

Dutch law is applicable to all agreements which are to be concluded by the supplier, which shall always be concluded under the applicability of these conditions. The convention for the International Sale of Goods shall not apply.