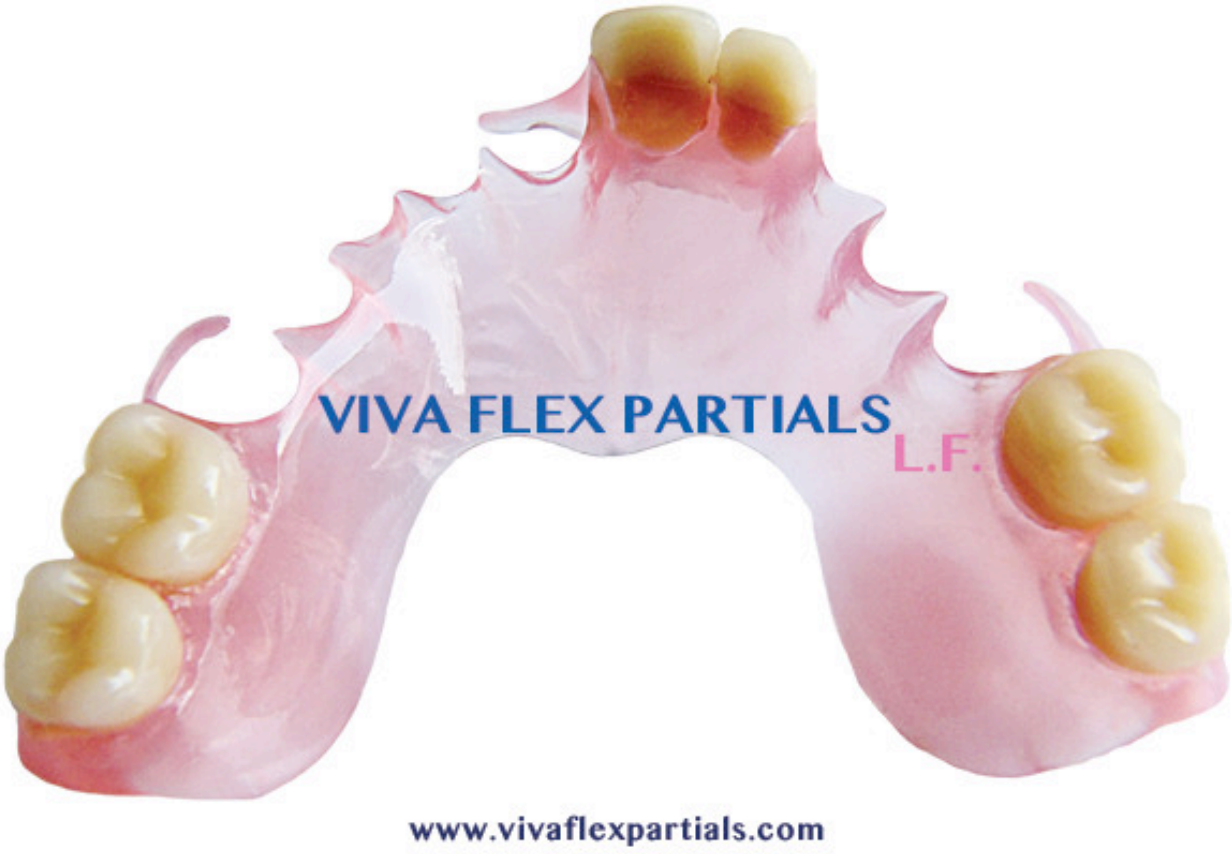
DENTAL FLEX ITALIA®

dental innovation

PACKAGE INSERT

REMOVABLE DENTAL PROSTHESIS

VIVA FLEX PARTIALS L.F.



Section 1

Declaration of conformity
About the Documentation
Manufacturer information
Attached documents

DECLARATION OF CONFORMITY

CE

The undersigned: *Gianfranco Guerra*

As legal representative of the company: ***Dental Flex Italia S.n.c.***

Based in: **Via Montevergine, 62 – Ospedaletto d'Alpinolo (AV) – 83014 -- Italy**

VAT number: **02570240644**

Declare

That the product: **Material Polyamide**

Model: **VIVA FLEX PARTIALS L.F.**

Code: **VFPLF2016**

Year of construction: 2016

It was built to the following rules:

- Directive 93/42 / EC also known as Directive concerning medical devices.
- Directive 2007/47 / EC amends Directive 93/42 / EC
- UNI EN ISO 20795-1: 2013 Dentistry - Polymer base - Part 1: Polymers bases for dental prostheses
- UNI EN ISO 14233: 2003 Dentistry - Raw materials based on polymers
- UNI EN ISO 1942: 2011 Dentistry - Vocabulary

And therefore it complies with regulations in force

Data **02/01/2016**

Signature

Rev. 0

Declaration of conformity

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INFORMATION ON THE MANUFACTURER

Name Legal Representative	Gianfranco
Surname Legal Representative	Guerra
Enterprise	Dental Flex Italia S.n.c.
Company headquarters: Street and City	Via Montevergine, 62 – Ospedaletto d'Alpinolo (AV) – 83014 - Italy
VAT number	02570240644
Product name	Removable dental prosthesis **VIVA FLEX PARTIALS L.F.** L.F.
Tel. Office	+39 0825 - 691237
Fax.	+39 0825 - 691237
Email	gianfranco@dentalflexitalia.eu
Website	www.dentalflexitalia.eu
Product link (if available)	https://vivaflexpartials.com/product/viva-flex-partials-lf

AUTHORIZED SERVICE

Technical assistance may only be carried out by the firm Dental Flex Italia S.n.c. and authorized personnel

PRESENTATION OF THE DOCUMENT

NOTE

UPON RECEIPT OF VIVA FLEX PARTIALS L.F. PRODUCT, BEFORE ATTEMPTING ANY OPERATION OF USE, PLEASE READ CAREFULLY THIS PACKAGE INSERT.

This document contains instructions for the implementation and processing of thermoplastic material VIVA FLEX PARTIALS L.F.

The document consists of several sections, each of which addresses a number of topics, divided into chapters and paragraphs. The general index lists all the topics of the entire insert.

Page numbering is progressive and on each page shows the number of the same. This document is for enforcement personnel, control and preservation of the Medical Device (DM) in question, and it relates to the service life after its production and sale.

In the event that the material is subsequently sold to third parties for any reason (sale, exchange, test or any other reason), VIVA FLEX PARTIALS L.F. it must be delivered with full documentation.

The information contained in this document are not intended to and cannot replace the knowledge and experience possessed by the professional who will use it, which in any case lies exclusively the responsibility of the application in the mouth.

Before starting any work on any model / patient, you need to have read the entire document and thus deepen the argument relating to the operations envisaged.

This document contains proprietary information and cannot be even partially provided to third parties for any purpose and in any form, without the prior written consent of the manufacturer.

The manufacturer declares that the information contained in this leaflet is consistent with the specifications and safety of the medical device, which the leaflet refers.

Certified copy of this document is filed in our technical database, kept by the manufacturer.

The manufacturer disclaims any documentation that has been produced, released or distributed by herself or by his authorized representative.

Section 2

Warranty
General safety rules
Technical features
General description
Use and not intended use

Warranty

The guarantee terms are listed in full in the purchase contract. They have value only and exclusively if the thermoplastic material VIVA FLEX PARTIALS L.F., pursuing the object of removable dental prostheses, it is used under conditions of intended use.

To the exclusion of the information provided, any manipulation or modification to the thermoplastic material VIVA FLEX PARTIALS L.F. by persons or companies not authorized, determines the termination of the guarantee.

The guarantee does not extend to damage caused by inexperience or negligence, or by poor maintenance or failure.

The products we sell are warranted regarding the materials are subject to the following conditions:	
1	*The guarantee is valid for a period of twelve (12) months.*
2	*The Manufacturing Company assumes the commitment to replace at its discretion parts of wrong manufacture, only after careful monitoring and detection of poor construction.*
3	*The buyer always pays the cost of transport and / or shipping.*
4	*During the warranty period, the product replaced, become the property of the manufacturer*
5	*This warranty can benefit only the original purchaser who has complied with the directions of normal storage in the package insert. Our responsibility Warranty expires when: the original owner disposes of the properties of the product, or changes are made to the same.*
6	*The warranty does not cover damage caused by excessive stress such as the application of VIVA FLEX PARTIALS L.F. after the finding of an anomaly, the use of methods of exercise not adequate and the failure to follow the cleaning instructions.*
7	*The manufacturer assumes no responsibility for any difficulties, which may arise in the use or resale abroad due to the provisions in force in the country where the product was sold.*
8	*The defective product must be delivered to Manufacturing Company for replacement; otherwise the replaced part, will be charged to the purchaser.*
9	*The warranty does not cover damage caused by excessive forces, such as the application of the thermoplastic material VIVA FLEX PARTIALS L.F. after the finding of an anomaly, the use of methods of exercise not adequate, and the failure to follow instructions of use.*

Notice: if it should appear necessary to use the warranty, please provide the following information:

1	*Typology*
2	*Date of purchase (the presentation of proof of purchase)*
3	*Detailed description of the problem*

NOTE

FAILURE TO FOLLOW THE INSTRUCTIONS FOR USE OF THERMOPLASTIC FLEX VIVA PARTIALS, DESCRIBED IN THIS DOCUMENTATION WILL RESULT IN FORFEITURE OF TERMS OF WARRANTY.

Warning

The staff assigned to the application and conservation of VIVA FLEX PARTIALS L.F., should read the package insert, paying particular attention to the general safety and the implementing rules contained in the sections relating to the operations of its competence.

This chapter describes the general safety rules to be observed during any operation carried out with VIVA FLEX PARTIALS L.F. Intervention procedures, described in subsequent chapters, must be carried out respecting both the manner of performance indicated, both the general safety of this chapter.

The safety rules and procedures for use of this document is a complement to the general rules of safety at work which have to be respected by the professional who applies VIVA FLEX PARTIALS L.F..

Different countries may have different regulations regarding safety. It declares that in all cases in which the rules of the leaflet were in conflict or reductive than the rules of the sector or country in which the Medical Device is used, the rules of the sector or the nation will still have priority over those of value manuals.

NOTE

THE MANUFACTURER MAY NOT BE HELD LIABLE IN ANY EVENT FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OBTAINED FROM THE USE OF DENTAL IMPLANTS MADE OF THE MATERIAL TERMOPLSTICO VIVA FLEX PARTIALS L.F., BY PROPERLY TRAINED PERSONNEL OR THAT IT HAS MADE USE INPROPIO, AS WELL AS FROM 'FAILURE OF PARTIAL SAFETY RULES AND PROCEDURES DESCRIBED IN THE MANUAL INTERVENTION.

The non-observance of the application and how it is stored in the package insert also determines the cancellation of the warranty terms.

Generality

The main purpose of this leaflet is to bring in a simple and gradual operator to accident prevention regulations and the rules of conduct that are the basis of a correct and safe use of the Medical Device (D.M.) by preventing, as far as possible, the injuries from occurring.

The provisions of the law are briefly listed as not to burden the structure of the book, but they do offer a good reference for those who wish to expand this topic.

With the entry into force of the Decree. n. 626 of 19/09/1994, as amended (81/08), the legislator has introduced the principle that all the special equipment to be used by the operator only after proper training and specific. This training should ensure that the use of the product is made properly, given the risks that may be caused to themselves or others. Therefore, the use of these medical devices should only be given to personnel and that have previously read the leaflet.

Safety regulations

If you experience an anomaly of any kind to the thermoplastic material:

- Do not start any operation application.
- Contact your service representative (see **AUTHORIZED SERVICE**).

If you feel the need to perform an action or not provided in a method different from that indicated by the manual before proceeding consult the manufacturer to test its feasibility.

The insert shall be guarded by staff who have been assigned the task of preserving and applying the Medical Device (D.M.) In the event of damage or loss, may be required by the Employer to the internal security service / manufacturer a certified copy, we recommend keep a backup in a place where it can not be damaged or lost.

CAUTION

AS IT WOULD BE IMPOSSIBLE TO DESCRIBE ALL OPERATIONS WHICH MAY NOT OR CAN BE DONE, YOU FEEL THAT ALL OPERATIONS (OTHER THAN NORMAL) THAT ARE NOT EXPRESSLY DESCRIBED IN THE PRODUCT MANUAL, ARE YOUR NOT BE PERFORMED.

DESCRIPTION AND TECHNICAL DATA

General description

Thermoplastic material of granular appearance, used for the realization of dental prostheses partial, full and maintainers removable.

THE PRODUCT IS PROVIDED IN A GRANULAR FORM (LOOSE) OR DOSED PACKED IN ALUMINIUM CARTRIDGES, READY TO USE.

Measurement Product

Granular

Composition

Composition (% in weight)
Polyamide polymers PA66

Technical features:

Melting range (°C)	240-300°C
Working temperature (°C)	290°C
Electrical conductivity (m/Ωmm2)	1.00E+11 (Ω ·m)
Elongation %	>50%
Density (g/cm^3)	1.00
Flexural strength	ASTM D790: 60

Expiration

Indefinite

Identification plates

The package of VIVA FLEX PARTIALS L.F. has a label on which shows the identity of the product and the main technical data.


The material is disposable


Obligation to read the leaflet

Production lot


Non-recyclable material


CE mark


Manufacturer

The label also shows the CE marking.

INTENDED AND NOT INTENDED USE

Intended

The thermoplastic material VIVA FLEX PARTIALS L.F. is a medical device for the realization of rails removable dental prosthetic. It is to be used only and exclusively for the realization of prosthetic articles, such as:

- PARTIAL DENTURES
- COMPLETE DENTURES
- RETAINERS
- BITES

Not intended use

There is no use different from those described in paragraph **INTENDED**.

It is also absolutely forbidden:

- The use of VIVA FLEX PARTIALS L.F. for uses other than dental.
- Reuse of thermoplastic VIVA FLEX PARTIALS L.F.. The use of excess parts, such as channels, spurs or other types of residues, following the first injection, no need to be used. The use of these raises the manufacturer from any responsibility for its use.

NOTE

THE MANUFACTURER CANNOT BE RETAINED IN NO EVENT BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES FOR USE NOT EXPECTED OF DENTAL IMPLANTS.

ANY USE NOT INTENDED MEDICAL DEVICE (D.M.) LEADS ALSO INVALIDATE THE TERMS OF WARRANTY.

Limits of *MEDICAL DEVICE (D.M.)*

Avoid building prosthesis with VIVA FLEX PARTIALS L.F. making thickness of the plaque bearing their teeth less than 1.5 / 2.00 mm.

Make sure the clasps perform their action retention only on the teeth and the mucous membranes, in order to avoid side effects to the patient.

Avoid building prosthesis without having first conducted a careful analysis of the model, by the dental.

During the phases of adaptation of the prosthesis to the duplicate model or to the master, to adjust the insertion of the prosthesis, so as to allow the patient an easy maneuver of insertion and extraction.

Avoid creating mechanisms interlocking of the prosthesis, particularly hard.

Make all the necessary evidence of insertion of the prosthesis and sealing, during the making of construction and finishing.

The prosthesis must be delivered to the doctor or who for them, only after the engineer has determined that all the steps and procedures required have been complied with.

Verify that the status of teeth is optimal, and that are secure in the oral cavity.

Avoid building prosthesis on teeth particularly extrusions presenting instability of position.

Make sure that the impression, taken by the dental assistant, on which are going to build the prosthesis, is perfectly faithful to that of the mouth of the patient, in order to avoid imperfections of shape.

The optimum maintenance of the device includes a scrupulous hygiene from the holder.

Carefully brush the dentures after meals brushing it under running water, preferably with a special brush.

When the carrier does not want to wear the prosthesis is recommended to keep it in water.

It is important that the carrier insert the prosthesis manually, until it has reached its correct position. Avoid at all cost to force the positioning of the prosthesis in the mouth or trying to insert it by tightening/closing the mouth.

For any information regarding changes recordings of the prosthesis, solely contact your doctor or professionals.

RESIDUAL RISKS

DANGER

ONLY A PROFESSIONAL THAT PREVIOUSLY HAS READ THE PACKAGE INSERT CAN MAKE STORAGE AND APPLICATION OF D.M.

- The place where you do the application of the prosthesis must have a minimum illumination of 200 lux.
- You have established a section on "Storage" to prevent the professional retains VIVA FLEX PARTIALS L.F. in places not appropriate or that may damage it.
- They were not detected any side effects for the patient on which it will be used D.M.
- **NEVER** expose the product to an open flame and / or heat.
- It has established a paragraph "**Limits of D.M.**" to prevent the professional uses the D.M. incorrectly or for operations not provided.
- This prosthesis can be used as a medical device only by specialized and enabled according to the instructions provided.

Section 3

Use

Use

For a correct application of the thermoplastic material VIVA FLEX PARTIALS L.F., and in order to provide a medical device capable of meeting the patient's requirements, it is essential to pay meticulous attention during the design stages, construction and finishing of the artefact.

1: Analysis of the impression

Make sure the doctor or whoever they have provided a 'preliminary impression correct, that is a mark readable, detailed, and has all the conditions to be able to be used and allows the realization of a precise prosthesis.
In the case where the preliminary impression appears to be inaccurate, it is absolutely necessary; provide an individual print holder, which can collect all details of the palate, necessary in order to achieve a correct device.

2: Model analysis

Once you have the model (development of the impression taken with the individual tray) and verified the accuracy of the details, you can proceed to the analysis of the model and the design of the prosthesis.

It is essential to run a silicone model ALWAYS. In the event, are no large undercuts, disparallelism, or other potential problems due to the different inclinations of the teeth, you should delete these angles, with the help of wax on the MASTER model. Subsequently, to dub the model downloaded.

Avoid at this stage the annulment of the undercuts.
In the case in which processing of the model analysis, eliminating undercuts for duplication, it is important to remember to leave them always in the negative, in order to ensure proper retention of the denture in the oral cavity.
In the case in which the axes of insertion are all put in parallel, the prosthesis will be devoid of retention.
The cases where they exist, which do not have large undercuts, duplication may be made without making wax in the angles of insertion of the prosthesis, and then duplicate the model without the addition of wax.

3: Design of plaque and tooth set

After the step of duplication, you can continue with the design and installation of the artificial teeth.

It is advisable to design the contours of the prosthesis, and then the plaque and the clasps with a pencil, before applying the wax sheet.

Depending on the size of the palate or the number of teeth and clasps to be built, we execute the drawing.

Following applies the wax paper.
The wax must be heated to make it more malleable and quickly adapted to the model. That done, it must be trimmed precisely to the design that we made earlier.

At this point we start the teeth setup.
It is essential to perform during the tooth set "**THE MECHANICAL RETENTION**".
Mechanical retention gives the mechanical bond between the tooth and thermoplastic material, which will allow the tooth to stay firmly in place during chewing.
The tooth needs to be drilled from right to left direction, or vice versa. Subsequently, a hole is drilled at its base, in this way, we will make the so-called "**T**" shape retention.

Retention or hole must be done with a ball cutter and use a diameter appropriate to the size of the tooth.
It is to avoid the mounting of the teeth in direct contact with the ridge of the model. This might cause bottlenecks and so prevent the material to flow correctly during injection, thus causing deficiencies.
The teeth are mounted leaving a minimum of 1 mm of wax under the teeth.

Always guarantee a thickness of 0.5 to 1.00 mm of material, between the artificial tooth and the natural one, in proximity of the clasps.

In order to give the right thickness to the arm of the hook, and consequently to avoid that the stresses can weaken the area and cause the detachment of the hook by the artificial tooth, with relative loss of retention, it is essential not to mount the artificial tooth too close behind of the natural.

When the installation has been completed, and the prosthesis is articulated antagonist model, it is advisable, (flesh- not I understand) the prosthesis.

Consequently, it adds a layer of melted wax, both on the plate than on the wax sheet, adapted on the design of the clasps. This will optimize the modeling and the procedure to flasking.

THICKNESS MODELING RECOMMENDED:
Palatal thickness from **1.5 to 2.00 mm**
Buccal and Lip flange thickness from **1.5 to 2.00 mm**
Clasps thickness from **1.00 to 2.00 mm**
Lingual flange thickness from **1.2 to 2.00 mm**
Lingual Mandibular Connector **1.7 - 2.0 mm**

4: SETTING UP MODEL AND FLASKING OPERATION

Eliminate all undercuts on the model, before proceeding to flasking.
When the model has been prepared, it shall conduct the base of the flask.

Kneading a quantity of gypsum sufficient to fill the base of the flask. Subsequently, adapt the model, taking into account that the floor of the palate of the same will have to be aligned with the central hole of the flask in the back.

When the plaster will be solid, it proceeds to the construction of the injection channels, which may be 2 or 3.
The injection channels must have a diameter of 7 mm.

Avoid creating sharp corners, the material inside the canal will flow in a straight or slightly curved.
Is necessary to isolate the plaster surface of the base, with an insulator alginic acid. This must be done before proceeding with the casting in the second part of the muffle, the so-called "the counter".

When the plaster of the counter will be cured, we must immerse the flask in a pot with hot water for at least 8 minutes.
After 8 minutes the flask should be open and "defatted", with hot water and steam, in order to remove any residual wax.
Subsequent to the complete elimination of the wax, it is necessary to isolate both the base of the flask that the counter with at least 2 coats of alginate at a distance of 5 minutes from each other.

In the event that you decide to run a pre-heating of the flask at 80° C, to ensure that the surface is dry, before the injection is advisable to rerun another coat of insulation.
The preheating should be done always having the flask open.

Injection:

When the flask is ready, make sure the pins (4) are well tight, before placing the flask onto the system.

Select a program on the machine, the melting temperatures must be set to 290ºC degrees, melting time is 15 minutes and the cooling time under pressure for 90 seconds.

Start the heating cycle of the machine and bring it to a temperature of 290ºC degrees.
When the machine has reached this temperature, lubricate the cartridge with a silicon compound, or spray (also silicone-based), insert the cartridge in the oven and immediately place the flask onto the oven, finally close tightly the clamping arm of the flask.

The machine will perform the injection cycle according to the data set.

When the cycle is finished, remove the flask from the machine and let it cool for at least 30 minutes, avoiding putting it under cold water.

Before opening the flask unscrew the 4 pins. Carefully proceed to break the plaster and avoid using hammers; you should take advantage of the use of dental forceps.

Finishing and Polishing:

Once removed, the denture from the flask, cut the injection channels with a separating metal disk.

For roughing the prosthesis, use carbide burs with cross-cut.

Adapt the prosthesis to the model very carefully.
For special cases, help with lacquer or carbon paper, to act on real points that hinders the insertion of the prosthesis on the model.

When the prosthesis has been adapted to the model, verifying its accuracy, it will be possible procedures to the polishing step.

To remove scratches left by the cross-cut cutter on the prosthesis, we recommend the use of strips of sandpaper cut by hand
The grain 220 is recommended, this does not overheat the material and eliminates scratches, restoring a smooth and compact surface ready for the passage of pumice.

Pumice is used with a brush of black hair hard, it is also advisable, to keep the prosthesis always wet with pumice during this phase.

Subsequently, a diamond paste needs to be applied, using a very soft (white) brush, to impart gloss to the prosthesis.

Finally, the prosthesis should be cleaned with soap and warm water, before handing it to the clinician.

It is advisable for the carrier to carefully clean of the prosthesis during the day. Clean the prosthesis at least twice a day, with running water and hard brush, to remove any buildup of food that have been deposited during the chewing.

When the prosthesis is not worn, it will be immersed in a container with water.

It is recommended for the patient, to do a check at least every six months to assess the state of retention of the prosthesis.

Section 4

Storage and Disposal

Storage

Qualified and authorized personnel must perform preserving operations.

When not using the prosthesis VIVA FLEX PARTIALS L.F., it must be kept in a glass of water.

Disposal

VIVA FLEX PARTIALS L.F., when produced according to criteria of strength, durability and flexibility, allowing the use of it for many years. Upon reaching the end of its service life, it should be withdrawn under the conditions that it cannot be used any longer and disposed.

The material of construction of the medical device does not require special disposal procedures. In case of disposal please refer to local regulations for the disposal of plastic waste.

The ability to reuse some parts is strongly discouraged and it is subject to the user's own responsibility and professional ethic.

NOTE

THE MANUFACTURER IS NOT RESPONSIBLE FOR DAMAGE CAUSED BY THE ARTIFACT DEVELOPED USING VIVA FLEX IF UNDER DEVELOPMENT HAVE NOT USED IN FULL VERSION, THE TERMS OF USE OF THIS PACKAGE INSERT.
THE MANUFACTURER IS NOT RESPONSIBLE FOR ANY DAMAGE TO PERSONS OR PROPERTY RESULTING FROM THE USE OF RECOVERY PARTS USED AFTER PROSTHESIS HAS BEEN DISPOSED.