Instructions for Use Flexcera™ Base Ultra+

Light Curable Resin

Introduction

Flexcera™ Base Ultra+ is a light-curable resin for the additive manufacturing of individual and removable full and partial denture bases. It has been optimized for use with Desktop Health's Einstein™ and Einstein™ Pro XL 3D printers and EnvisionTEC's Perfactory® Envision One cDLM ® and Perfactory® D4K Pro 3D printers and may only be used together with these printers and the corresponding software systems. *Flexcera™ Base Ultra+* is a medical device classified per U.S. Food and Drug Administration (FDA) as Class 2 (21 CFR 872.3760). Full and partial denture bases from *Flexcera™ Base Ultra+* may only be manufactured by dental technicians and dentists, and must be inspected by authorized practitioners, such as dentists, before they are released to the patients.

Dentures from *Flexcera™ Base Ultra+* light curable resin are custom-made products for daytime use and intended exclusively for one patient. The target group is patients with a total or partial loss of teeth within one or both jaws, whereby high-risk patients are excluded (see Contraindications).

The minimum approved wall thickness is 2.5mm and the maximum approved wall thickness is 10mm. The following Instruction for Use includes safety and environmental information, manufacturing instructions, and post-processing procedures of the product, which must be strictly adhered to.

Indication

Flexcera™ Base Ultra+ is a light-curable resin indicated for the fabrication of denture bases fabricated in dental laboratories for full and partial removable dentures. The material is an alternative to traditional heat-curable and auto polymerizing resins. *Flexcera™ Base Ultra+* is intended exclusively for professional dental work. Fabrication of denture bases with *Flexcera™ Base Ultra+* requires a computer-aided and manufacturing (CAD/CAM) system that includes the following components: digital denture base-files based on a digital impression, a digital light processing (DLP) printer, and curing light equipment.

Flexcera™ Base Ultra+ is available in the following colors:

Light Pink | Pink | Medium Pink | Dark Pink | Dark Meharry

Contraindications

Flexcera™ Base Ultra+ should not be used for purposes other than those identified herein. Any deviation from these instructions for use may have negative effects on the physical and/or chemical qualities of the resin and the biocompatibility of the end product. Dental applications from *Flexcera™ Base Ultra+* should not be used in patients if there are known allergies to any of the ingredients (see Composition). Possible side effects may include shortness of breath, gastrointestinal complaints, dizziness, anaphylactic reactions, or shocks, itching and tearing (watery) eyes, headaches, or reactions of the skin or mucous membranes such as irritation, rash, swelling, inflammation, redness, wheals or blisters or other allergic reactions.

Composition

Flexcera™ Base Ultra+ is based on the same composition as *Flexcera™ Smile Ultra+:*
Acrylates, methylacrylates, methacrylated oligomers and monomers, photo initiators, colorants/dyes, fillers and absorbers

Warnings

- Review the SDS prior to use.
- *Flexcera™ Base Ultra+* may only be used for the production of individual and removable full or partial denture bases. Any clasps needed as part of the denture design must also be made of *Flexcera™ Base Ultra+*. Any deviation from the Instruction for Use can negatively affect the chemical and physical properties of the finished product. Consequently, the biocompatibility of the denture cannot be guaranteed.
- *Flexcera™ Base Ultra+* may not be used for the production of fixed dentures, cover dentures, implant retained dentures, attachment prothesis, telescope prothesis, bar prothesis or any other type of denture with retaining elements, which need to be integrated additionally.
- Do not substitute any of the components of the device system, i.e., device photopolymer materials, bonding systems, scanners, 3D printers, post-curing units, CAD/CAM software, templates, and tools. Use only those specifically identified in this labeling. Unauthorized changes may result in a device that is outside of specification. Contact the manufacturer for compatible components.
- Maintain and calibrate equipment according to manufacturer instructions.
- Products from *Flexcera™ Base Ultra+* light curable resin cannot be sterilized. See section 12 for disinfection procedure.
- Wear protective gloves, protective clothing, eye protection, face protection when handling *Flexcera™ Base Ultra+* light curable resin.
  In case of skin contact with the resin, wash with plenty of water.
- In case of eye contact, rinse cautiously with water for several minutes. Remove contact lenses, if necessary and easy to do. Continue rinsing. Consult a physician.
- If swallowed, immediately call the poison center.
- Any patients who come in contact with products from *Flexcera™ Base Ultra+* light curable resin must be informed of potential side effects before use (see Contraindications).

Precautions

- Wear protective gloves, protective clothing, eye protection, face protection.
- Use in appropriately ventilated area. Avoid breathing dust/fume/gas/mist/vapors/ spray.
- *Flexcera™ Base Ultra+* light curable resin must be stored in the original material bottle between 41°F (5°C) and 86°F (30°C).
- *Flexcera™ Base Ultra+* light curable resin must be protected from exposure to light, as spontaneous polymerization is possible. The bottle must be tightly closed after every usage and material removal. The resin must be used prior to the expiration date printed on the label.
- As described in Storage Conditions, when using an Einstein™, after 4 builds, mix the material remaining in the material tray thoroughly and return it to the bottle. Shake the bottle vigorously before utilizing the resin again.
- Denture bases (full or partial) must be protected from exposure to light while not in use.

Storage Conditions, Expiry Date and Re-use of Material

- *Flexcera™ Base Ultra+* light curable resin must be stored in the original material bottle between 41°F (5°C) and 86°F (30°C).
- While removing the resin it must be protected from exposure to light, as spontaneous polymerization is possible. The bottle must be tightly closed after every usage and material removal.
- An expiration date is displayed on the label of every material bottle. The use of expired material is not permitted.
- The resin inside the machine material tray can be re-used for several build jobs. If the level in the material tray is too low for subsequent jobs, resin from the bottle can be added as necessary. If the material is not in use, it must be filled back into the bottle. For further information on re-using and mixing material, please check the printer's User Manual.
- When using an *Einstein*™ 3D Printer, after 4 builds, mix the material remaining in the material tray thoroughly and return it to the bottle. Shake the bottle vigorously before utilizing the resin again.
- Denture bases (full or partial) must be protected from exposure to light before the final use, while not in use, and during storage.

Notes on Disposal

Dispose of *Flexcera™ Base Ultra+* light curable resin and material bottle in accordance with local regulation. Manufactured dentures which are used on patients must be disposed in accordance with local regulation due to the risk of contaminated by substances of human origin.

Use of Software Systems and Products from Other Manufacturers

The use of certified software systems for generating the STL data depends on the users assessments.

The use of additional medical products or auxiliary products to manufacture full and partial dentures must strictly adhere to:

- *VITA VIONIC BOND from VITA Zahnfabrik* as adhesive for assembling conventionally manufactured artificial teeth within the denture base (not necessary for 3D-printed teeth made of *Flexcera™ Smile* or *Flexcera™ Smile Ultra+)*

The use of any other additional medical products or auxiliary products, for example light-curing stains and composites for individualization or conventionally manufactured artificial teeth to be assembled with a denture base made from *Flexcera™ Base Ultra+* depend on the users assessments of those products.

Delivery Unit, Symbol Explanation

Delivery Unit:

Flexcera™ Base Ultra+ is available in containers of 1 kg.

Symbol explanation:

LOT	Batch number		Protect from sunlight
	Expiration date (YYYY-MM-DD)		Follow Instruction for Use
	Manufacturer		Temperature limit
REF	Catalogue number		Manufacturing date (YYYY-MM-DD)
Rx Only	Prescription device labeling statement	UDI	Unique device identification

Manufacturing Instructions

Supplies for Fabrication

1. Desktop Health 3D printer: Einstein™ or Einstein™ Pro XL
   or
   EnvisionTEC 3D printer: Perfactory® Envision One cDLM® or Perfactory® D4K Pro.
2. Material tray for use with *Flexcera™ Base Ultra+* light curable resin only. Order printer-specific parts from EnvisionTEC or authorized distributors.
3. *Flexcera™ Base Ultra+* light curable resin. Order from Desktop Health™ or authorized distributor.
4. *Flexcera™ Smile* or *Flexcera™ Smile Ultra+* light curable resin or conventionally fabricated artificial teeth (PMMA). Order *Flexcera™ Smile* or *Flexcera™ Smile Ultra+* from Desktop Health™ or authorized distributor.
5. VITA VIONIC® BOND for assembling conventionally manufactured artificial teeth (PMMA) only.
6. *Flexcera™ Base Ultra+* material tag/RFID card (shipped with the material bottle).
7. For the material mixing procedure: Ceramic balls and bottle roller machine.
8. Envision One RP (version 1.35.5715 or later).
9. Buildstyle for *Flexcera™ Base Ultra+* . Contact EnvisionTEC Technical Support if buildstyle is not supplied with the machine.
10. File in. stl format
11. Starter Kit (included with the purchase of the 3D printer), provided scraper (Einstein™, Perfactory® Envision One cDLM®, Perfactory® D4K Pro) or material mixing cards (Einstein™ Pro XL), and cone-shaped filters.
12. Paper towels.
13. Cone-shaped funnel.
14. Personal protective equipment, as per SDS.
15. Magnetic stirrer with bar, or lab shaker.
16. Isopropyl Alcohol min. >96%.
17. Otoflash G171 curing unit
    or
    Wicked Engineering CureBox Plus.
18. Pipette.
19. Dental laboratory handpiece and milling accessories and scalpel.
20. Standard dental polishing equipment.

Design Information

The scanning and construction of patient's STL data is the responsibility of the customer. Only trained dental personnel must perform the scanning and design. Further, certified software must be used, such as from e.g., 3Shape A/S.

Full dentures made of *Flexcera™ Base Ultra+* must be designed without any additional fixtures to increase holding force. Design the denture base using the certified software based on the digitalized data obtained from the bite registration process. The minimum approved wall thickness is 2.5mm., Fig. 1.

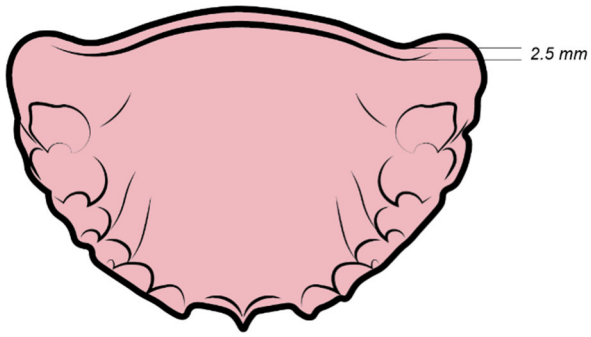

Fig. 1 *Minimum wall thickness*

A connector must be added to the design of the lower denture base to ensure the stability of the part during fabrication and accuracy of the part's dimensions/fit once finished. The connector designs in Fig. 2 are permitted (Figure 2A is recommended, as it will require the least amount of material while ensuring high accuracy. The connectors in Figure 2A, as well as the automatic orientation and supporting can be achieved by using the Autopilot function of EnvisionOne RP version 1.35.5715 or later).

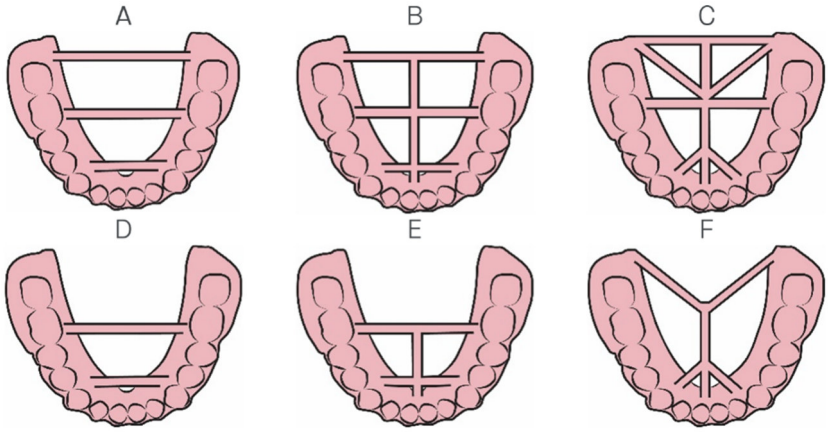

Fig. 2 *Validated connector designs for lower denture base*

The thickness of the denture base when measured at the cross-section of a tooth pocket/alveoli should not be thinner than 1mm.

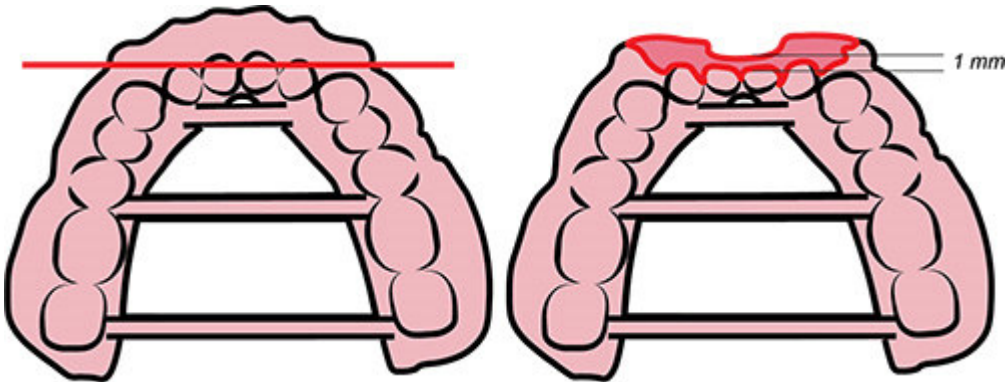

Fig. 3 *Cross-sectional minimum thickness of denture base at tooth pocket/alveoli*

Partial dentures made of *Flexcera™ Base Ultra+* must be designed without any additional fixtures to increase holding force, except for the clasps. The minimum approved wall thickness of the denture as well as for the clasps is 2.5mm.

Prepare Print

Preparing the resin

Flexcera™ Base Ultra+ light curable resin must be properly mixed before use. Prepare the resin: Shake the resin bottle vigorously by hand. Add ceramic balls to the bottle and then place the resin bottle on a bottle roller for a minimum of 12 hours.

1. Setup the 3D printer for *Flexcera™ Base Ultra+* light curable resin (see the User Manual for the specific 3D printer used).
2. Fill the material tray.
3. Use the spatula from the Starter Kit (Einstein™, Envision One cDLM®, D4K Pro) or a material mixing card (Einstein™ Pro XL) to carefully mix the resin in the material tray. Mix until there is a uniform color. Take care not to damage the surface of the material tray.

To avoid contamination, a separate material tray dedicated to *Flexcera™ Base Ultra+* must be used. A material tag (RFID card) is shipped with the *Flexcera™ Base Ultra+* resin bottle. Place the material tag on the RFID tag reader on the 3D printer, Fig. 3. The card must remain on the reader for the duration of the print.

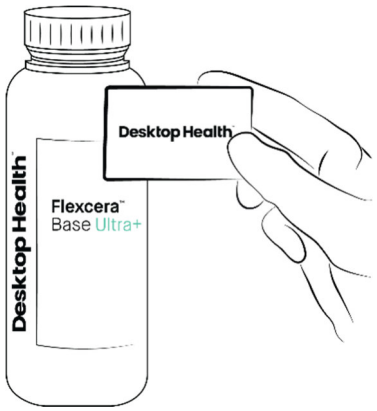

Fig. 4 *Placing material tag*

Prepare STL for 3D printing, Software Considerations

To prepare the .stl file for 3D printing and generate the support structures, use the Envision One RP (version 1.34.5673 or later).

1. Connect the *Flexcera™ Base Ultra+* buildstyle to the software. Contact EnvisionTEC Technical Support to receive a buildstyle for *Flexcera™ Base Ultra+*.
2. For accurate results, full denture bases must be built vertically orientated to the build platform, with supports connecting only to the labial border. (Recommendation: Use the "autopilot function: full denture bases" of the Envision One RP (version 1.34.5673 or later)). In this orientation, the manual post processing of the sides in direct contact with the oral mucosa will be avoided.
3. For accurate results, partial denture bases must be built horizontally orientated to the build platform. The supports should be connected to the area of the denture that does not make contact with the patients gingiva.

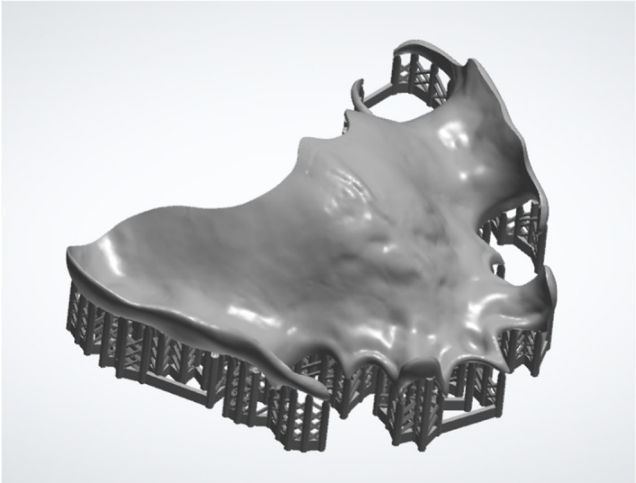

Fig. 5 *Partial Denture with Supports*

4. Transfer a created Job file (STL files of denture bases added with supports) to the printer. See the printer's User Manual / Software User Manual.

Start Print

Start the printing process as described in the printer's User Manual.

Post-Processing Instructions

Remove Printed Parts from 3D Printer

When the printing process is complete, carefully remove the models from the build platform.

> **Important:** Always wear personal protective equipment when interacting with uncured material.

1. Open the printer's hood.
2. Remove the build platform from the printer.
3. Place the build platform on a sturdy surface. Use the provided scraper from the Starter Kit to carefully remove all models from the build platform. Place models on a clean paper towel and protect from ambient light.

Clean Printed Parts

Set up the magnetic stirrer with a bar or lab shaker in the Post Processing area and add Isopropyl Alcohol (min. >96 %) into an appropriately sized container. See the stirrer / shaker manual for setup instructions.
Clean the printed parts using the following procedure:

1. Clean in Isopropyl Alcohol (min. >96 %), which was not pre-used for cleaning any other material, for a maximum of 5 minutes in the stirrer or lab shaker (no ultrasonic bath). Clean and rinse gaps separately under pouring conditions.
2. Dry with compressed air.
3. Clean in another fresh Isopropyl Alcohol bath (min. >96 %), which was not pre-used for cleaning any other material, for a maximum of 2 minutes in the stirrer or lab shaker (no ultrasonic). Clean and rinse gaps separately under pouring conditions.
4. Dry with compressed air.
5. Parts must be completely dry e. g.airdry @ 15min.
6. Remove the supports with a scalpel or similar tool. The connectors of the lower full denture bases will not be removed in this step.

Assemble Dentures

Denture bases printed from *Flexcera™ Base Ultra+* may be bonded to denture teeth printed from *Flexcera™ Smile* or *Flexcera™ Smile Ultra+* light curable resin, or conventionally fabricated artificial teeth (PMMA).

3D printed artificial teeth

In this case, the denture bases printed using *Flexcera™ Base Ultra+* must be uncured before assembling.
If using *Flexcera™ Smile* or *Flexcera™ Smile Ultra+*: The 3D printed teeth must be uncured, unpolished without any grinding prior attaching to the denture. See *Flexcera™ Smile* or *Flexcera™ Smile Ultra+* IFU for manufacturing instructions.

1. For uncured 3D printed artificial teeth use the pipette to place drops of *Flexcera™ Base Ultra+* resin in the alveoli of the uncured denture base, Fig. 4. Immediately after, place the individual teeth, segments or arches into the alveoli of the denture base with the uncured *Flexcera™ Base Ultra+* resin and proceed to post-curing in step 2. To avoid overcuring, place all individual teeth, segments or arches, then proceed to step 2.

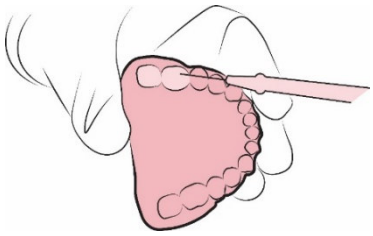

Fig. 4 *Use pipette to place drops of uncured Flexcera™ Base Ultra+ in alveoli*

2. Post-cure the part using the light curing unit:
   Otoflash G171 Parameters: 2x4000 flashes (4000 flashes per side);
   or
   Wicked Engineering CUREbox Plus 2x20 minutes (20 minutes per side) at 45°C.
   Do not stack dentures or allow parts to touch in the light curing unit. Parts will be hot after post-curing. They may also feel soft and malleable. Allow to cool and rest. Be careful not to bend, drop or adjust, until the part is at room temperature. Remove gently from curing unit and allow to rest uninterrupted until at room temperature.

   Note: Using an alternative light source may result in an insufficient curing, which may adversely affect biological and mechanical properties.

Conventionally manufactured artificial teeth (PMMA)

In this case, the denture bases printed using *Flexcera™ Base Ultra+* must be cured before assembling and the alveolar surfaces of the denture base need to be roughened.
For bonding, the conventionally manufactured artificial teeth (PMMA) need to be roughened before assembling and VITA VIONIC® BOND from VITA Zahnfabrik, which is a self-curing two-component bonding system, needs to be used. This bonding system must not be used in combination with the Otoflash curing unit.

1. Post-cure the denture base using the light curing unit:
   Wicked Engineering CUREbox Plus 2x20 minutes (20 minutes per side) at 45°C.
   Note: Using an alternative light source may result in an insufficient curing, which may adversely affect biological and mechanical properties.

2. Sandblast or grind the alveolar surfaces of the denture base and the tooth neck of the conventionally manufactured artificial teeth (PMMA) with sand blasting corundum or with a dental laboratory hand piece and milling accessories.

3. Apply VITA VIONIC® BOND according to IFU from manufacturer and fix the teeth to the base.

Individualization

In order to achieve a highly aesthetic result, Flexcera Base Ultra+ can be individualized and customized externally after completion of the post-curing process.
For this purpose, the surface must be roughened (grinding or sandblasting - please follow the instructions for use of the respective individualization system) and then cleaned with compressed air until it is completely residue-free, dry, and free of dust and dirt (please use an "oil-free compressor" for this purpose).
Now the individualization process can be started according to the instructions for use of the individualization system used.

Finish Dentures

1. Remove connector(s) with dental laboratory handpiece and cutting disc or similar tool.
2. Use a commercial dental laboratory handpiece to clean the remaining support structures and remove excess resin around the teeth.

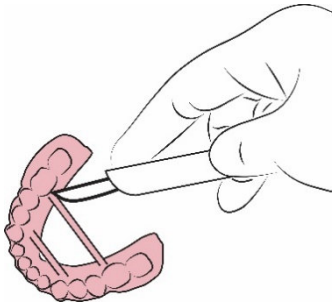

Fig. 6 *Remove connector*

3. Polish the surface with a commercial dental laboratory handpiece or dental polishing machine.
   Use the device according to instructions for use by the manufacturer. Due to the polishing process, minimal differences in fit can occur. Therefore, the printed product should be inspected on a dental model after processing.
4. Post-cure the product in the Otoflash G171 with 1000 flashes, or with the Wicked Engineering CUREbox Plus for 5 minutes at 30°C.
5. The product can now be used on the patient.

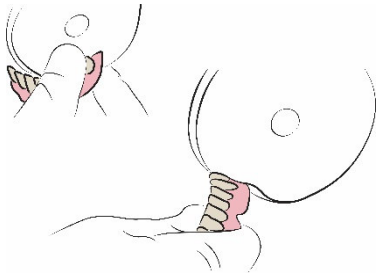

Fig. 7 *Polishing dentures*

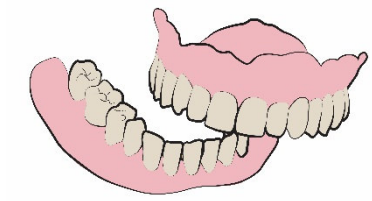

Fig. 8 *Finished dentures*

Disinfection and Sterilization

Full or partial denture bases made of *Flexcera™ Base Ultra+* light curable resin can be disinfected with any of the following disinfectants:

- 70% Ethanol solution in water
- Green&Clean AD
- MD 520
- PrintoSept-ID
- Dentavon

The disinfecting solutions must be used according to the manufacturer's instructions.
Products from *Flexcera™ Base Ultra+* light curable resin cannot be sterilized.

Cleaning Instructions for Patients

The denture can be cleaned by the patient with clear water, a toothbrush, and toothpaste. Avoid abrasive or whitening agents in some kinds of toothpaste which can damage the surface of the denture. After cleaning with clear water, the denture should be dried and not soaked in liquid.

Note: Care should be taken to ensure that the dentures are not shipped or stored soaking in water as this can adversely affect the mechanical properties.

Reporting Undesirable Effects

In the event of adverse effects, reactions, or similar occurrences arising from the use of these products, including those not listed in this Instruction for Use, these must be reported immediately by opening a support ticket via the website https://etec.desktopmetal.com/support/ or https://health.desktopmetal.com/support/ticket/ or by contacting your local distributor.

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Legal Disclaimer

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Rx Only