



# Smart Dentin Grinder™ User Guide

Autologous Bone Grafting

## About This Guide

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Thank you for purchasing the Smart Dentin Grinder™, which enables you to create a patient's own autologous bone graft within less than 15 minutes!

Thanks to this solution, extracted teeth are no longer considered to be clinical waste. Extracted teeth can now be used as an autologous bone graft, which is the golden standard of grafting. With Smart Dentin Grinder™, a few short steps easily transform an extracted tooth into a sterile and clean dentin particulate ready for grafting.

We are certain that this autologous graft will provide you with optimal results.

This user guide is intended for dental practitioners. It describes how to use the Smart Dentin Grinder.

- **Chapter 1, Introducing the Smart Dentin Grinder Process**, page 7, introduces the Smart Dentin Grinder and describes its components and how it works.
- **Chapter 2, Using the Smart Dentin Grinder**, page 13, describes how to transform an extracted tooth into a sterile and clean particulate dentin ready for grafting.
- **Appendix A, Specifications**, page 27, describes the specifications for the Smart Dentin Grinder.
- **Appendix B, Labeling**, page 28, shows the label that appears on the Smart Dentin Grinder.

## Important Notice

# Important Notice

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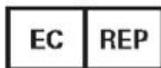
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## Documentation Conventions

### NOTE:

Notes provide additional important information.

### TIP:

Tips provide shortcuts or special guidance that may enable optimal performance.

### WARNING!

Warnings indicate conditions or practices that could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

### CAUTION:

Caution indications relate to conditions or practices that are potentially hazardous that may result in minor or moderate injury to the user or damage to the equipment or other property. Caution indications may also be used to indicate practices necessary for effective use of the device.

## Safety Information

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### **WARNINGS!**

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Adhere to the following warnings and safety information for the use of this device:

- The Smart Dentin Grinder must only be used with its original parts.
  - No modification of the Smart Dentin Grinder is permitted.
  - The Smart Dentin Grinder must only be operated in accordance with the instructions provided in this user guide and for the purpose described in this user guide.
  - Keep the Smart Dentin Grinder away from heat or open flame.
  - To avoid electric shock or device malfunction, liquids must not be allowed to enter the device.
  - Do not plug in the Smart Dentin Grinder while barefoot or with wet hands.
  - Do not use the Smart Dentin Grinder in an explosive environment or in the presence of flammable anesthetics or gases.
  - Do not use the Smart Dentin Grinder in an oxygen-rich environment.
  - The Smart Dentin Grinder should not be operated when there is any visible physical damage, such as cracks, breaks and so on.
- 

### **CAUTIONS:**

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- This device is not defibrillation proof.
  - The device is intended for non-continuous operation.
  - Storage and transportation temperature is between -5°C to +55°C.
  - The Smart Dentin Grinder must only be serviced by an authorized representative.
-

# 1 Introducing the Smart Dentin Grinder Process

This chapter introduces the Smart Dentin Grinder™ and describes its components and how it works.

## What is the Smart Dentin Grinder?

The Smart Dentin Grinder provides an innovative solution for autologous dentin grafting. It enables you to convert extracted teeth into a bacteria-free particulate dentin ready for transplant within less than 30 minutes.

## Device Intended Use

The Smart Dentin Grinder grinds extracted teeth into particles and sorts these particles according to size. This process creates bacteria-free sterile particulate that is ready for autologous tissue engineering by grafting it into fresh sockets and bone defects.

- A)** For autologous use only. Device should **ONLY** be used to produce graft from the patient's own tooth to be used for that particular patient
- B)** The Grinding Chamber and Cleanser Kit are a single use items and should not be reused under any circumstance.

## Indications for Use

- The Smart Dentin Grinder is intended to be used by dental practitioners.
- The Smart Dentin Grinder is to be used for patients that:
  -  Have one or more non-essential teeth that are specified to be extracted for autologous grafting by a dentist.
  -  Require bone grafts.

## Contraindications

- Teeth that have undergone root canal fillings should be discarded and not used for grafting.

## Smart Dentin Grinder Components

The following lists the contents of the Smart Dentin Grinder package.

### **WARNING!**

Check the package contents for damage. If any of the contents of the package are damaged, do not use the Smart Dentin Grinder and return it to your supplier.



Figure 1: Smart Dentin Grinder Components

Each of the components of the Smart Dentin Grinder is described below:

- **Single-use, disposable Chamber**, page 9
- **Dappen dish / Containers**, page 10

## Single-use Disposable Chamber

The Smart Dentin Grinder operates with a single use, disposable chambers which must only be used for a single patient during a single session. Each chamber is provided in a sealed packaging.

Each chamber is marked with the following symbol  indicating that it is a single-use part.



Figure 2: Single-use, Disposable Chamber

Each disposable chamber has a see-through cap. When the cap is open, you can see the grinding blade and particulate sieve, as shown below:



Figure 3: Grinding Blade and Particulate Sieve

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The Particulate Drawer has two compartments (sub-drawers), as shown below:

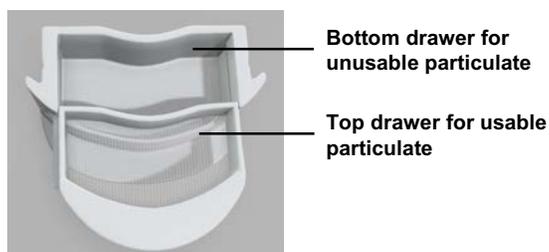


Figure 4: Particulate Drawer Compartments

### NOTE:

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Contact your local distributor when you need more sterile disposable chambers.

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## Dappen dish / Containers

The Smart Dentin Grinder package is provided with a dappen dish / container and holder that is used to store the particulate during the autoclave sterilization process.

### WARNING!

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Do not reuse the same chamber or containers for different patients or for the same patient in different sessions.

## How Does the Smart Dentin Grinder Work?

The Smart Dentin Grinder grinds a patient’s own teeth into dentin particulate, separates the particulate into specific sized particles. The dentin graft is then cleansed using an autoclave that is available in every dental office.

This procedure transforms any patient’s tooth into a sterile particulate dentin that is grafting bio-material for a highly predictable autologous graft.

The following provides an overview of how the Smart Dentin Grinder works. Detailed operation instructions are provided in *Chapter 2, Using the Smart Dentin Grinder* on page 13.

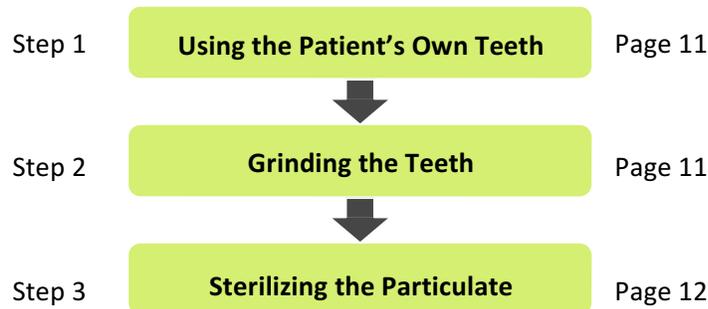


Figure 5: Stages of the Smart Dentin Grinder Process

### Step 1, Using the Patient’s Own Teeth

One or more of the patient’s own teeth are extracted in the usual manner and then cleaned.

### Step 2, Grinding the Teeth

The Smart Dentin Grinder is specially designed for grinding teeth into particulate dentin. It grinds the teeth into particles and then sorts them according to size.

Dentin particles of suitable size for implanting (between 250 and 1,200 microns) are automatically stored in the Smart Dentin Grinder’s top drawer compartment.

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Large particles can be reground in order to obtain more particles of the proper size (between 250 and 1,200 microns).

Extremely small dentin particles (below 250 microns) fall into its bottom drawer compartment for disposal or use in conjunction with the larger particles. Efficiency is approximately 95%, meaning that typically 95% of the extracted tooth can be used for dentin bone grafting.

The Smart Dentin Grinder enables you to configure the grinding time of the teeth and the sorting time of the particulate.

### NOTE:

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Grinding speed and vibration intensity are predefined and cannot be changed.

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## Step 3, Sterilizing the Particulate

Once the dentin graft particulates have been produced by The Smart Dentin Grinder, they are poured into the provided autoclave safe, glass container and will pass an autoclave standard sterilization cycle. We typically recommend to cover the glass container with autoclave safe wrapper. We recommend that the sterilization cycle be 20 minutes in 270 degrees Fahrenheit or 130 degrees Celsius.

## 2 Using the Smart Dentin Grinder

This chapter describes how to transform an extracted tooth into a sterile and clean particulate dentin ready for grafting.

### Workflow Overview

The following describes the workflow for using the Smart Dentin Grinder.

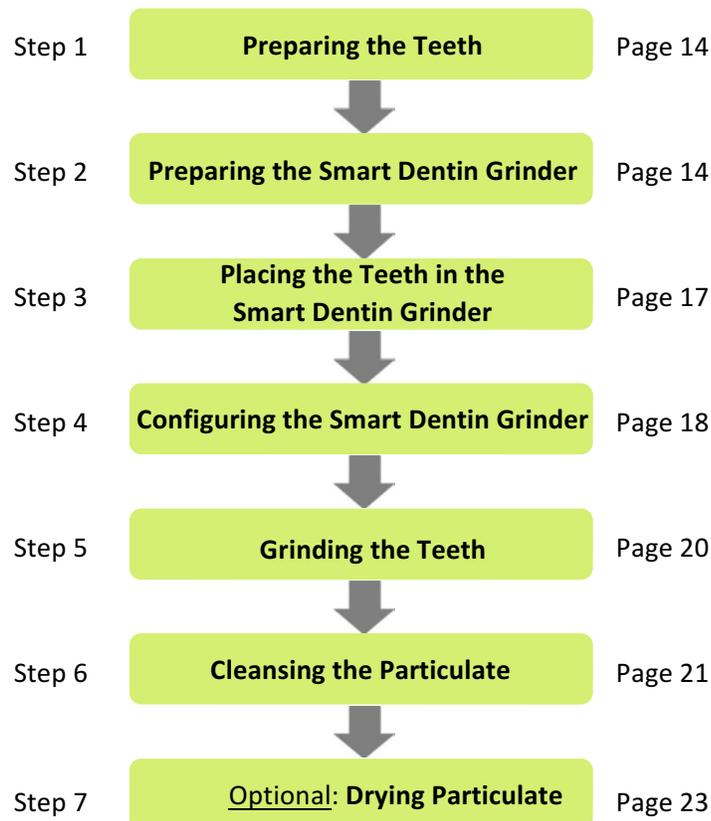


Figure 6: Using the Smart Dentin Grinder – Workflow Diagram

## Step 1, Preparing the Teeth

 Only teeth that have undergone root canal fillings are not suitable. All other teeth can be used.

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**WARNING!**

 **Do not use teeth that have root canal treatment.**

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► **To handle the extracted teeth:**

- 1** Extract one or more of the patient's own teeth in the usual manner. This should be done during the same treatment session as the grinding, not before.
- 2** Use a tungsten bur to remove all cavities and artificial material from the extracted tooth, so that only the clean tooth dentin remains.  
Artificial material to be removed may include fillings, crowns and any prosthetic materials.
- 3** Remove all surface debris, especially on the root.

## Step 2, Preparing the Smart Dentin Grinder

This step describes how to prepare the Smart Dentin Grinder for a procedure.

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**CAUTION:**

The Smart Dentin Grinder vibrates and therefore must be kept on a stable surface away from the table's edges.

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**CAUTION:**

Each chamber comes in plastic packaging. Do not open its packaging before this point.

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**WARNING!**

Each disposable chamber must only be used for a single patient and only once.

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## Smart Dentin Grinder User Guide

### ► To prepare the Smart Dentin Grinder:

- 1 Place the Smart Dentin Grinder on a flat and stable surface or tabletop.
- 2 Plug in the Smart Dentin Grinder into a standard electrical outlet.
- 3 Open the chamber's plastic packaging.
- 4 Put the chamber on the top of the Smart Dentin Grinder, as shown below:



Figure 7: Attaching the Chamber

- 5 Align the small arrow on the chamber with the one in the center of the grinder, as shown below:



Figure 8: Aligning the Arrows

## Smart Dentin Grinder User Guide

- 6 Turn the chamber counterclockwise to lock it in position. When locked, the **LOCK** indicator arrow on the chamber is to the right of the arrow in the center of the grinder.



Figure 9: Chamber is Locked

- 7 Switch on the Smart Dentin Grinder, as shown below:



Figure 10: Switching On the Smart Dentin Grinder

The **POWER** indicator should light up on the operation panel, as shown below:



Figure 11: Power Indicator

## Step 3, Placing the Teeth in the Smart Dentin Grinder

The Smart Dentin Grinder is a specially designed for grinding teeth into particulate dentin. The instructions below can be used for between one and six teeth at once.

**NOTE:**

If you wish to process more than six teeth for the same patient in the same session, then simply perform this entire process on a few teeth at a time.

► **To grind the teeth:**

- 1 Remove the cap of the sterile disposable chamber, as shown below:



Figure 12: Removing the Chamber Cap

- 2 **Please** dry the teeth with air before placing them in the grinding chamber!
- 3 Place the prepared teeth on the grinding sieve next to the blades, as shown below:

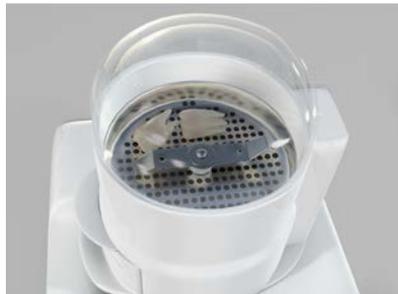


Figure 13: Placing the Teeth in the Smart Dentin Grinder

The teeth must have been prepared, as described in the *Step 1, Preparing the Teeth* section on page 14.

- 4 Close the chamber cap and twist it counterclockwise so that it clicks into place.



Figure 14: Closing the Chamber Cap

**NOTE:**

The chamber cap has a safety latch so that the Smart Dentin Grinder stops immediately when the cap is open.

## Step 4, Configuring the Smart Dentin Grinder

The Smart Dentin Grinder enables you to configure its grinding time and sorting time.

 **TIP:**

We highly recommend grinding less time as opposed to more time. The reason is that grinding too long produces unusable particulate (particles of less than 250 microns). Therefore, it is much preferable to grind less time and then to repeat the grinding process by pressing the **START** button again.

**NOTE:**

The Smart Dentin Grinder retains the latest configuration that you set (as described on the next page) unless it is powered off.

► **To configure the Smart Dentin Grinder:**

- 1 Grinding time refers to the number of seconds that the Smart Dentin Grinder spins its blade in order to break down the dentin material into particles.

To configure Grinding Time:

☞ Press the **GRIND** button. The **GRIND** indicator lights up.

☞ Press the **UP** and/or the **DOWN** button as many times as needed in

order to set

the preferred Grinding Time.

We recommend setting grinding time to **3 seconds**, as shown below:



Figure 15: Grinding for 3 Seconds

- 2 Sorting Time refers to the number of seconds that the Smart Dentin Grinder vibrates in order to filter the particles through the grinder's sieve and the removable chamber's drawers.

To configure the Sorting time, in seconds:

☞ Press the **SORT** button. The **SORT** indicator lights up.

☞ Press the **UP** and/or the **DOWN** button as many times as needed in order to set the preferred Sorting Time.

We recommend setting sorting time to **20 seconds**, as shown below:



Figure 16: Sorting for 20 Seconds



**TIP:**

To display the currently configured Grinding Time, simply press the **GRIND** button.

To display the currently configured Sorting Time, simply press the **SORT** button.

## Step 5, Grinding the Teeth

► **To start the Smart Dentin Grinder:**

- 1** Press the **START** button to start the grinding process. The sorting (vibrating) Process starts automatically afterwards.
  -  Dentin particles smaller than 1,200 microns fall into the top drawer.
  -  The bottom of the top drawer is mesh that allows particles smaller than 250 microns to fall into the bottom drawer. These particles are to be disposed of.
  -  This leaves particles of between 300 to 1,200 microns in the top drawer. The Resulting particulate dentin in this top drawer may be two to three times the Volume of the original root.
- 2** Click the **START** button again to grind for another 3 seconds and to sort for another 20 seconds.
- 3** If large pieces are left in the grinding chamber, then press the **START** button again to grind for another 3 seconds and to sort for another 20 seconds.

If the teeth appear to be ground already, but the particulate has simply not fallen through the grinding sieve holes, then set the Grinding to **0** and then press the **START** button again to only perform the sorting procedure.

## Step 6, Cleansing the Particles

► To cleanse the particles so that they are bacteria free:

- 1 Pull the chamber drawers out of the disposable chamber, as shown below:



Figure 17: Pulling Out the Drawers

- 2 Pull out/apart the top drawer compartment, which contains particles of between 250 – 1,200 microns, as shown below:

Bottom drawer compartment containing particles that cannot be used. Smaller than 250 microns.



Top drawer compartment containing particles that can be used. Between 250 – 1,200 microns.

Figure 18: Pulling Out the Top Drawer Compartment

- 3 Pour the contents of the top drawer compartment into one of the provided containers.



Figure 19: Harvesting the Implantable Particles

- 4 Insert the glass container into an autoclave sleeve or wrapper according to the autoclave specifications.
- 5 Run your autoclave on a normal cycle according to the recommendations of the autoclave manufacturer.

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**NOTE:**

We recommend that the sterilization cycle to be 20 minutes in 270 degrees Fahrenheit or 130 degrees Celsius.

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- 6 Leave the graft to cool down still covered with the autoclave sleeve for 2 minutes in room temperature. After that, the dentin graft is ready for use.
- 7 In order to gain a more putty like consistency for the graft, you can wet the graft with any conventional agents that are commonly used in grafting procedures such as saline, PBS, patient's own blood, and PRF. If excess liquid has been used, you can decant the excess by pipetting it out or by absorbing with a sterile dental gauze.

## Step 7, Storing the Particulate

► **To store the Particulate for future use:**

- 1** Once you've completed the cleansing step as described in Step 6, the dentin graft should be dry. At this time place the provided cover on the glass container and mark up the container with a non-erasable marker or sticker to label the name of the patient and the date of processing the tooth.
- 2** The container containing the graft should be stored in room temperature.
- 3** Prior to reuse of the dentin graft that was previously stored by / for the patient, Step 6 – Cleansing the Particles, needs to be repeated.

**Note:**

- Only use the glass containers supplied by Kometa Bio.
- Cover the graft while in the autoclave with a standard autoclave loose cover to prevent particulates from popping.

# A Specifications

The Smart Dentin Grinder has the specifications described below.

**Table 1: Smart Dentin Grinder Specifications**

Specification	Value
<b>Grind Mode</b>	
Operation Time (Sec.)	1~99 (Sec.)
Applied Voltage (V)	240 V AC
Frequency (Hz)	50 Hz
No Load Speed (rpm)	16000 rpm $\pm$ 10%
<b>Sort Mode</b>	
Operation Time (Sec.)	1~30 (Sec.)
Applied Voltage (V)	6 V DC
No Load Speed (rpm)	10000 rpm $\pm$ 15%
<b>Other Features</b>	
Style	Tabletop
Power Requirements	240 V AC
Machine Dimensions (mm x mm x mm)	120 x 168 x 113
Machine Weight (g)	1228
Cup Dimensions (mm x mm x mm)	76 x 101 x 90
Cup Weight (g)	178

## B Labeling

This appendix shows the label that appears on the Smart Dentin Grinder.

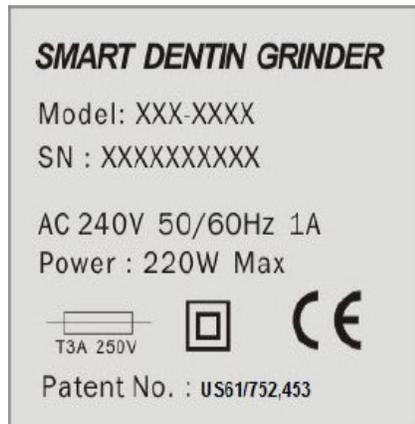


Figure 21: Smart Dentin Grinder Label

# Kometa-Bio International

## Limited Warranty Certificate

when new, are free of material defects and shall perform in accordance with Kometa Bio's specifications as outlined in the attached operation manual (the "Operation Manual").

This Limited Warranty is for a period of two years from the date of purchase of the Devices from Kometa Bio (the "Warranty" and "Warranty Period" respectively).

This Warranty is personal to the original purchaser and may not be transferred. Any sale, re-sale, rental, or other transfer or use of the Device covered by this Warranty to or by a party other than the original purchaser shall cause an immediate termination of this Warranty.

The Warranty will take effect upon providing the invoice for the Devices, as a proof for the time of purchasing and the name of the purchaser.

Kometa Bio may, at its sole discretion, either repair or replace any components of Devices found to be defective or non compliant with the Operation Manual specifications within the Warranty Period at no cost to the purchaser (other than the cost of shipment to Kometa Bio). In the case of a defect or malfunction within the Warranty Period, it shall be the purchaser's responsibility to notify Kometa Bio or one of its authorized agents or representatives of any such defect or non compliance.

This Warranty shall be valid only if the Devices are used in strict compliance with the Operation Manual. This Warranty shall not apply to damages occurring as a result of breakage, tampering, misuse, neglect, accidents, modification, disassembly or repairs made by parties not authorized by Kometa Bio or to damages during shipping.

Further, this Warranty does not apply:

- to the replacement of consumable items, supplies or accessories;
- to damage caused by use with non Kometa Bio approved consumables, attachments or accessories;
- to damage caused by re-use of the approved single-use consumable items;
- to damage caused as a result of accidents, theft, abuse, negligence, misuse, vandalism, corrosion, or any causes other than ordinary use for which the Device was designed;
- to damage caused as a result of alterations or repairs to the Device by anyone other than Kometa Bio or a Kometa Bio authorized service provider;
- to cosmetic damage including but not limited to, marks, scratches, dents, etc.; and
- If any Kometa Bio serial number has been removed or defaced.

This Warranty is exclusive of any and all other warranties, expressed or implied, including without limitation, the implied warranty of merchantability or fitness for a particular purpose.

Kometa bio shall not be liable to any person for any special, consequential or indirect damages, including, but not limited to, damages to or loss of property or equipment, loss of profit, loss of use of data, loss of revenues or damages to business or reputation arising from any cause whatsoever arising from or in any way connected with the manufacture, sale, handling, repairs maintenance or use of the device, whether or not kometa bio shall have been made aware of the possibility of such loss provided that it is not otherwise regulated by applicable law.

Notwithstanding any of the foregoing, kometa bio's liability for any claims arising out of or in connection with this warranty, shall in the aggregate, be limited to the total price paid for the device, if such liability does not arise from the gross negligence or fault of kometa bio.

Without limitation, kometa bio shall have no liability for any death, personal and/or bodily injury and/or damage to property or other loss whether direct, indirect, incidental, consequential or otherwise, in connection with or arising out of

or relating to the use of dentin graft produced by the device (e.g. Dental procedures) and the purchaser of the device agrees to indemnify kometa bio and hold it harmless from and against any and all claims, damages, losses, liabilities and

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