



Product Code	Item Description
DBL2-0090	MSi Kit (consisting of one of each of the components listed below)
DBL2-0091	MSi Snoring Appliance
DBL2-0092	MSi Excursive Plate
DBL2-0097	MSi Adjustment Screwdriver - Non Medical Device - for extra oral use
DBL2-0098	MSi Bite Right Jig

DESCRIPTION

The MSi Kit components consist of the MSi Snoring Appliance, MSi Excursive Plate, MSi Bite Right Jig and MSi Adjustment Screwdriver (non-medical device). They have been designed to be used in the fabrication and adjustment of a custom-made snoring device which is used to treat snoring and obstructive sleep apnoea.

INTENDED TARGET POPULATION

The MSi Kit is intended to be used on any patient (regardless of gender and ethnicity) from the age of eighteen (18) years onwards.

MATERIAL INFORMATION

The MSi Snoring Appliance and MSi Excursive Plate is constructed of medical grade 316 Stainless Steel. The MSi Bite Right Jig is constructed from ABS plastic.

INTENDED USE

The MSi Kit components; MSi Snoring Appliance and MSi Excursive Plate when fabricated into a custom-made snoring device is intended to be worn for a period of approximately eight (8) hours whilst the patient sleeps. The custom-made snoring device allows a patient's lower jaw (mandible) to be held in a forward position that will keep the airway open; in order to prevent or reduce snoring and sleep apnoea. The patient is able to speak and move the lower jaw in lateral positions (left and right); therefore, allowing the patient to sleep on the left / right hand side.

INDICATIONS

The MSi Kit components; MSi Snoring Appliance and MSi Excursive Plate have been designed to be used in the fabrication of a custom-made snoring device which is used to treat snoring and obstructive sleep apnoea. The MSi Bite Right Jig is considered an 'accessory device', as although it is provided with the MSi Kit, it is not essential. However, it is useful for non-experienced users as it takes away the guesswork associated with wax bite provision. The MSi Adjustment Screwdriver (non-medical device) is used by the Clinician and Patient to adjust the hook position of the custom-made snoring device until optimum position is found for snoring to cease, or be reduced.

INTENDED USERS

Professional use only. The MSi Kit is supplied to Dental Technicians to use in the fabrication of a custom-made snoring device. The Dental Technician makes the custom-made device to the clinicians prescription. The Dental Technician then provides the finished custom-made device to the Clinician to fit to the patient.

HOW TO FIT THE MSI SNORING APPLIANCE

- Place the upper part of the device (featuring the hook) in the mouth and push into place covering the upper teeth.
- Place the lower part of the appliance in the mouth and press into place covering the lower teeth.
- To locate the hook correctly, move the lower jaw forward until engaged.

TO REMOVE

- Ask the patient to push their lower jaw forward to disengage the hook.
- Ask the patient to use the edge to push the lower part of the appliance in an upwards direction and the upper part of the appliance in a downwards direction to dislodge from the teeth and remove.

It is important for the patient to take time to get used to the feel of the MSi as initially, it may feel uncomfortable. It is recommended that for the first week the patient should wear the device without any advancement with the MSi adjustment screwdriver.

1. Once the patient is used to the appliance, a gradual adjustment of the MSi snoring appliance is recommended (one turn of the screw; 0.5mm advancement a week) until the optimum position is found. It isn't simply a matter of the further forward the better; its about finding the 'optimum position' where snoring will cease or be reduced.

2. Use the MSi snoring appliance adjustment screwdriver to move the advancement hook forwards in a clockwise position.

3. Adjusting the MSi snoring appliance is easy with the specially designed MSi adjustment screwdriver. An indentation on the shaft of the MSi adjustment screwdriver helps to register a full turn of 360° degrees. The MSi adjustment screwdriver can always be positioned with the indentation visible.

4. Adjustments of the MSi snoring appliance should be made outside the mouth to ensure the MSi adjustment screwdriver is fully inserted and the hook thread is not adjusted to its full extent. Warning! If the MSi adjustment screwdriver is turned when fully extended and resistance is felt, you risk damaging the mechanism and a costly repair.

5. If no further adjustment is available, it can be repositioned by the manufacturer.

CONTRAINDICATIONS

• Not to be used on persons under eighteen (18) years of age.

NOT to be used on persons diagnosed with or that suffer from:

- Central sleep apnoea,
- Temporomandibular joint pain/disorder (TMJ),
- Severe respiratory disorders,
- Loose teeth/Crown,
- Advanced and Active Periodontal Disease,
- Nausea or vomiting,
- Nickel Chromium Allergy.

WARNINGS AND PRECAUTIONS

- Not to be used on patients with a known allergy to
- Do not use if packaging is damaged,

POSSIBLE ADVERSE EFFECTS

- Tooth discomfort/aching,
- Jaw discomfort after advancement,
- Excess salivation and/or dry mouth,
- Temporary alteration in the bite for the first hour in the morning.

INTENDED PERFORMANCE CHARACTERISTICS

The MSi Kit is intended to have the following performance characteristics and compatibilities:

- · Biocompatible (suitable for transient, invasive contact in the oral cavity),
- Able to be cleaned by the user without adversely affecting form, fit or function;
- Able to be stored in, and shipped between facilities without sustaining physical damage adversely affecting form, fit or function,
- Each component/device is intended to be used with each other without adversely affecting form, fit or function.
- The MSi Kit components; MSi Snoring Appliance and MSi Excursive Plate are for Single Patient Use only.
- The MSi Bite Right Jig is single use only.
- These components are classified as Class I medical devices, under Rule 5 and are supplied non-sterile
- The MSi Adjustment Screwdriver is a reusable non-medical device and is supplied non-sterile.

CLINICAL BENEFITS TO PATIENTS

- An alternative treatment for those who cannot tolerate CPAP therapy,
- Prevents or reduces snoring and reduces sleep apnoea,
- Improves the supply of oxygen to the body,
- Improves quality of sleep for patient and sleeping partner reduced daytime sleepiness,

- Good patient compliance,
- Patient comfort

PATIENT INFORMATION

A patient Instructions for Use leaflet is provided with the MSi Kit for the clinician to pass to the patient after the custom-made snoring device has been fitted. The patient instructions for Use leaflet contain information on how to fit, remove and adjust the MSi custom-made shoring device. Instructions on how to clean the custom-made shoring device is also included.

The MSi custom-made snoring device is intended to be cleaned by the Dental Technician before being sent to the Clinician. Cleaning Instructions are provided in the Dental Technician Fabrication instructions. Cleaning Instructions are also provided in the patient Instructions for Use leaflet which is to be provided to the patient.

STORAGE

No special storage conditions necessary.

WARRANTY

2 years from date of purchase.

LIMITATION OF LIABILITY

Except where prohibited by law, DB Orthodontics will not be liable for any loss or damages arising from this product, whether direct. Indirect, special, incidental or consequential regardless of the theory asserted, including warranty, contract, negligence or strict liability. This limitation does not apply to third party personal injury claims.

BETURNING PRODUCT TO US

Products returned to us after use must have a decontamination certificate which testifies that the MSi Kit components have been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a delay in dealing with your enquiry.

SERIOUS INCIDENTS

Any serious incident that has occurred in relation to the device should be reported to the Manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

DISCLAIMER:

The MSi Kit provided by DB Orthodontics contains unfinished components, which are provided to a Dental/Orthodontic Laboratory to make a finished custom-made device. DB Orthodontics are a supplier of critical components and parts, needed by the end user. The components as provided by DB Orthodontics do not treat 'snoring and obstructive sleep apnoea' in their unfinished state. Once the components are assembled by the end user into a custom-made device, the finished custommade device is used to treat 'snoring and obstructive sleep apnoea'. As such, the Dental/Orthodontic Laboratory are the legal manufacturer and as such are responsible for the safety and performance of the custom-made device and for conformity with relevant regulatory requirements.

DOWNLOAD INSTRUCTIONS

PATIENT INSTRUCTIONS



CLINICAL INSTRUCTIONS



BITERITE INSTRUCTIONS



DB Orthodontics Limited Ryefield Way, Silsden, West Yorkshire, BD20 0EF, United Kingdom

Phone: +44 (0) 1535 656999 I Email: Sales@dbortho.com I Web: www.dbortho.com





The MSi is a Custom Made Device.