DTR Medical®

AN INNOVIA MEDICAL COMPANY

ORAL ROTATING BIOPSY PUNCH
Instructions for Use
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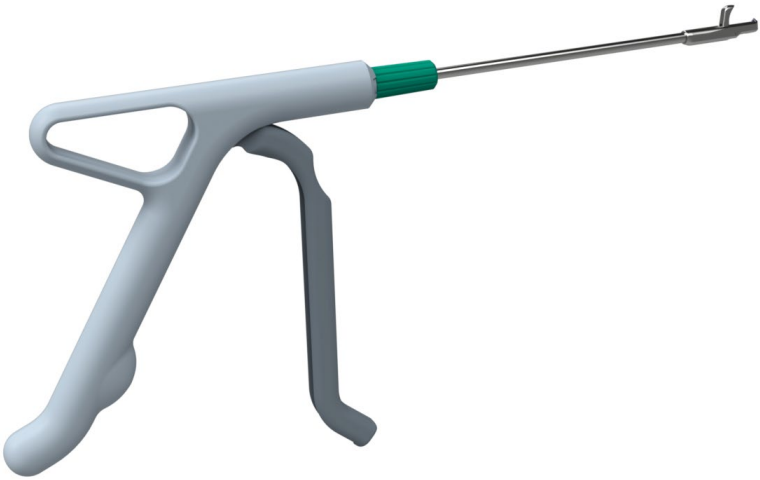
REF **OBR1001, OBRL1001**

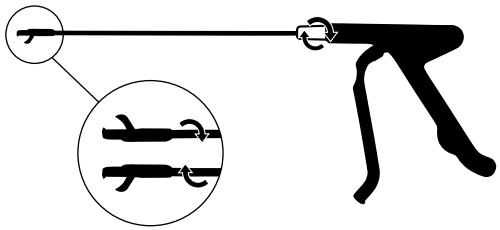


EN

DESCRIPTION
The Oral Rotating Biopsy Punch has been designed specifically for use in oral procedures to obtain a biopsy from the front of mouth, gums, tongue, soft palette and tonsil area. They are equipped with a pair of jaws at the end of a metal rod with a handle and trigger. The long metal construction ensures better access to the mouth or throat for the jaws, whilst the handle is operated outside. When the trigger is pulled the sharp jaw closes. This action removes a segment of Tissue for the Biopsy. The 360° rotation enables enhanced positioning and patient interaction. A straight, non-bendable forceps is very suitable for these procedures, a curved product is not essential.

MATERIALS OF CONSTRUCTION

Product Component	Details
Top Jaw	17-4 Precipitation Hardened Stainless Steel
Bottom Jaw	316 Stainless Steel
Tube	304 Stainless Steel
Handle	Polycarbonate (PC)
Trigger	Polycarbonate (PC)
Rotation Controller	Polycarbonate (PC)



INTENDED USE/INDICATIONS FOR USE
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INTENDED USER
The Oral Rotating Biopsy Punch is intended for use by Healthcare Practitioners trained in Biopsy sampling procedures. It must only be used by suitably trained and qualified staff. The product is intended solely for use in the medical sector and within a clinical environment. The user shall be familiar with the instrument before using it.

INDICATIONS, CONTRAINDICATIONS AND PATIENT SELECTION FACTORS
The Oral Rotating Biopsy Punch indicated for use in oral procedures to obtain a biopsy from the front of mouth, gums, tongue, soft palette and tonsil area.

The decision to proceed with biopsy in the following circumstances must be individualized to the patient's findings and the ability of the surgeon to minimize morbidity.

The following may be contraindications to biopsy, or they may alter the circumstances of the biopsy (office vs operating room):
- Bleeding diathesis secondary to anticoagulation, or significant coagulopathy
- Airway issues that could be exacerbated by the biopsy (If concerns regarding airway control exist [e.g., bleeding, edema], biopsy may be better performed in the operating room with the airway secured.)
- Lesion located near vital structures that could be injured by biopsy (e.g., lateral Pharynx near carotid artery)
- Medical conditions that do not allow for the use of local anaesthetics (these patients require general anaesthesia in the operating room)

PATIENT POPULATION
Anyone of any gender or any age in the human population that is identified as needing a oral surgical procedure.

WARNINGS AND PRECAUTIONS
The device is to be used by trained medical persons possessing the requisite skill and experience to use the device in accordance with the prevailing standards of medical practice and in conjunction with the instructions for this device.
- This product is supplied sterile in an undamaged, unopened package as a single use device. Do not resterilise or reuse.
- Before using, inspect package for punctures, tears, security of the seal or any other evidence of the sealed pouch having been compromised prior to placement of the contents in the sterile field.
- DO NOT USE if package is damaged.
- If the device accidentally becomes contaminated before treatment, do not use and dispose accordingly.
- Do not use after the expiration date.
- Do not use the device outside the intended use.
- Do not alter the instrument structurally, force it or bend it.
- Beware of the biting jaw being open during introduction into, advancement through and removal from the patients. When the jaws are open, damage to the patient, or device may occur.
- Instruments made from Stainless Steel may contain Nickel. Although the contact between instruments and patient is transient, it may cause an allergic reaction in patients with sensitivity to this material. Users should risk assess the use of the instruments in relation to the medical benefit of the procedure and take necessary precautions with patients with known sensitivity to nickel.

SHELF LIFE AND STERILITY
Instruments are supplied in a sterile condition, packaged individually and double-wrapped. The instruments are sterilized by exposure to gamma irradiation at a minimum dose of 25 kGy – indicated by the symbol on the label. They remain sterile as long as the package integrity has not been violated.

Packaging must be inspected before use. Do not use any component from an opened or damaged package.

The expiration date is printed on the label. Do not use instruments after the expiration date.

STORAGE AND HANDLING
Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, sunlight and temperature/humidity extremes.

Care must be exercised in handling of wrapped cases or individual instruments to prevent damage to the sterile barrier.

Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

TRANSPORTATION
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OPERATIONAL USE
Introduce the Oral Rotating Biopsy Punch through the mouth and position it proximal to the area of interest. Rotate the device as necessary using the green rotational element to ensure optimal position for biopsy and patient interaction. Position the device so the oral area of interest is between the jaws and pull the trigger to close jaws. Hold the trigger to preserve the biopsy sample just taken. Retrieve the removed segment of tissue for biopsy and collect it accordingly.

DEVICE DISPOSAL
Used devices should be disposed of as clinical waste. If unused, product in original packaging which has exceeded the declared shelf life should be removed from packaging and disposed of as clinical waste. Handle and dispose this product in accordance with accepted medical practice and with applicable local, state and national laws and regulations.

The Oral Rotating Biopsy Punch does not contain:
- Substances of human origin
- Animal tissues
- Dangerous or hazardous substances
- Radioactive material
- Any substance that may be a Medicinal Product as defined in Article I of Directive 2001/83/EC

HAZARDS ASSOCIATED WITH THE RE-USE OF SINGLE USE ONLY DEVICES:
1. Single use devices have not been validated for re-use. If you re-use a device you may be held Legally Liable for the safe performance.
2. Cross-contamination and infection risks to patients, including transmission of:
    - CJD & Variant CJD.
    - Prion Diseases.
    - Bacterial Endotoxins.
    - Hepatitis B & Hepatitis C.
    - Risks posed by HIV and AIDS.
3. Device failure through material fatigue or degradation caused by initial use and design:
    - Plastics: Can be weakened, warped or become brittle.
    - Metals: Can be damaged or subjected to rusting.
    - Other materials: May degrade, becoming unacceptable when compared to original manufacturing criteria.
4. Patient injury from device failure and/or chemical burns from residue of decontamination agents absorbed into the materials.

REPORTING PROBLEMS
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ES

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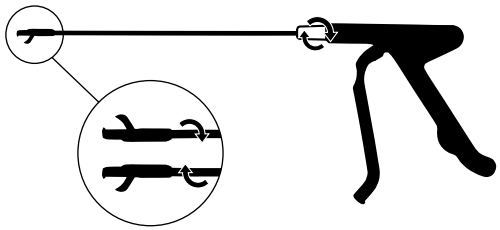

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IT

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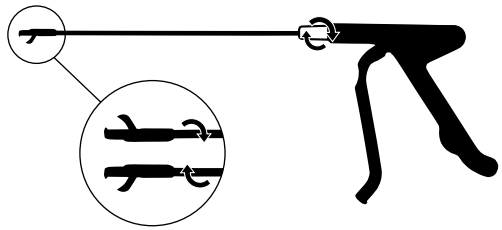

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DE

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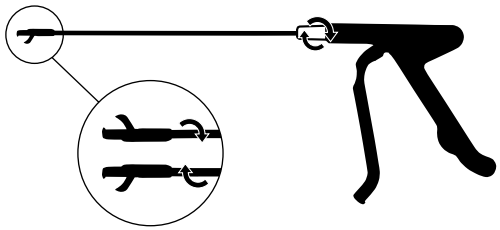

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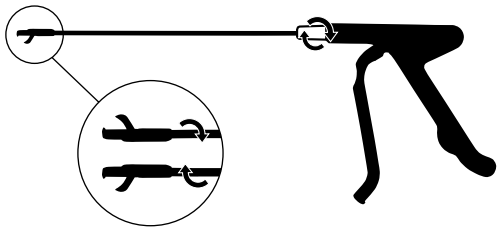

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INTENDED USER
The Oral Rotating Biopsy Punch is intended for use by Healthcare Practitioners trained in Biopsy sampling procedures. It must only be used by suitably trained and qualified staff. The product is intended solely for use in the medical sector and within a clinical environment. The user shall be familiar with the instrument before using it.

INDICATIONS, CONTRAINDICATIONS AND PATIENT SELECTION FACTORS
The Oral Rotating Biopsy Punch indicated for use in oral procedures to obtain a biopsy from the front of mouth, gums, tongue, soft palette and tonsil area.

The decision to proceed with biopsy in the following circumstances must be individualized to the patient's findings and the ability of the surgeon to minimize morbidity.

The following may be contraindications to biopsy, or they may alter the circumstances of the biopsy (office vs operating room):
- Bleeding diathesis secondary to anticoagulation, or significant coagulopathy
- Airway issues that could be exacerbated by the biopsy (If concerns regarding airway control exist [e.g., bleeding, edema], biopsy may be better performed in the operating room with the airway secured.)
- Lesion located near vital structures that could be injured by biopsy (e.g., lateral Pharynx near carotid artery)
- Medical conditions that do not allow for the use of local anaesthetics (these patients require general anaesthesia in the operating room)

PATIENT POPULATION
Anyone of any gender or any age in the human population that is identified as needing a oral surgical procedure.

WARNINGS AND PRECAUTIONS
The device is to be used by trained medical persons possessing the requisite skill and experience to use the device in accordance with the prevailing standards of medical practice and in conjunction with the instructions for this device.
- This product is supplied sterile in an undamaged, unopened package as a single use device. Do not resterilise or reuse.
- Before using, inspect package for punctures, tears, security of the seal or any other evidence of the sealed pouch having been compromised prior to placement of the contents in the sterile field.
- DO NOT USE if package is damaged.
- If the device accidentally becomes contaminated before treatment, do not use and dispose accordingly.
- Do not use after the expiration date.
- Do not use the device outside the intended use.
- Do not alter the instrument structurally, force it or bend it.
- Beware of the biting jaw being open during introduction into, advancement through and removal from the patients. When the jaws are open, damage to the patient, or device may occur.
- Instruments made from Stainless Steel may contain Nickel. Although the contact between instruments and patient is transient, it may cause an allergic reaction in patients with sensitivity to this material. Users should risk assess the use of the instruments in relation to the medical benefit of the procedure and take necessary precautions with patients with known sensitivity to nickel.

SHELF LIFE AND STERILITY
Instruments are supplied in a sterile condition, packaged individually and double-wrapped. The instruments are sterilized by exposure to gamma irradiation at a minimum dose of 25 kGy – indicated by the symbol on the label. They remain sterile as long as the package integrity has not been violated.

Packaging must be inspected before use. Do not use any component from an opened or damaged package.

The expiration date is printed on the label. Do not use instruments after the expiration date.

STORAGE AND HANDLING
Sterile, packaged instruments should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, sunlight and temperature/humidity extremes.

Care must be exercised in handling of wrapped cases or individual instruments to prevent damage to the sterile barrier.

Sterile instrument packages should be carefully examined prior to opening to ensure that package integrity has not been compromised.

TRANSPORTATION
The instruments are supplied in their designated packaging. This packaging ensures that every instrument is kept in a way that they do not receive any damage and that their functionality is preserved during transportation.

OPERATIONAL USE
Introduce the Oral Rotating Biopsy Punch through the mouth and position it proximal to the area of interest. Rotate the device as necessary using the green rotational element to ensure optimal position for biopsy and patient interaction. Position the device so the oral area of interest is between the jaws and pull the trigger to close jaws. Hold the trigger to preserve the biopsy sample just taken. Retrieve the removed segment of tissue for biopsy and collect it accordingly.

DEVICE DISPOSAL
Used devices should be disposed of as clinical waste. If unused, product in original packaging which has exceeded the declared shelf life should be removed from packaging and disposed of as clinical waste. Handle and dispose this product in accordance with accepted medical practice and with applicable local, state and national laws and regulations.

The Oral Rotating Biopsy Punch does not contain:
- Substances of human origin
- Animal tissues
- Dangerous or hazardous substances
- Radioactive material
- Any substance that may be a Medicinal Product as defined in Article I of Directive 2001/83/EC

HAZARDS ASSOCIATED WITH THE RE-USE OF SINGLE USE ONLY DEVICES:
1. Single use devices have not been validated for re-use. If you re-use a device you may be held Legally Liable for the safe performance.
2. Cross-contamination and infection risks to patients, including transmission of:
    - CJD & Variant CJD.
    - Prion Diseases.
    - Bacterial Endotoxins.
    - Hepatitis B & Hepatitis C.
    - Risks posed by HIV and AIDS.
3. Device failure through material fatigue or degradation caused by initial use and design:
    - Plastics: Can be weakened, warped or become brittle.
    - Metals: Can be damaged or subjected to rusting.
    - Other materials: May degrade, becoming unacceptable when compared to original manufacturing criteria.
4. Patient injury from device failure and/or chemical burns from residue of decontamination agents absorbed into the materials.

REPORTING PROBLEMS
Healthcare professionals, users and patients should report any suspected serious incident related to the device by informing the manufacturer at www.dtrmedical.com/contact and the competent authority, ministry of health, or delegated agency in which the suspected serious incident has occurred.

For patients in Australia please visit the Therapeutic Goods Administration (TGA) website: www.tga.gov.au.

SYMBOL REFERENCE TABLE / SYMBOL REFERENCE TABLE / SYMBOL REFERENCE TABLE / SYMBOL REFERENCE TABLE / SYMBOL REFERENCE TABLE	
REF	Indicates the manufacturer's catalog number so that the medical device can be identified / Indicates the manufacturer's catalog number so that the medical device can be identified / Indicates the manufacturer's catalog number so that the medical device can be identified / Indicates the manufacturer's catalog number so that the medical device can be identified / Indicates the manufacturer's catalog number so that the medical device can be identified
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified / Indicates the manufacturer's batch code so that the batch or lot can be identified / Indicates the manufacturer's batch code so that the batch or lot can be identified / Indicates the manufacturer's batch code so that the batch or lot can be identified / Indicates the manufacturer's batch code so that the batch or lot can be identified
EC REP	Indicates the authorized representative in the European Community/European Union / Indicates the authorized representative in the European Community/European Union / Indicates the authorized representative in the European Community/European Union / Indicates the authorized representative in the European Community/European Union / Indicates the authorized representative in the European Community/European Union
CH REP	Authorized Representative in Switzerland / Authorized Representative in Switzerland / Authorized Representative in Switzerland / Authorized Representative in Switzerland / Authorized Representative in Switzerland
Rx Only	Caution: US Federal law restricts this device to sale by or on the order of a physician / Caution: US Federal law restricts this device to sale by or on the order of a physician / Caution: US Federal law restricts this device to sale by or on the order of a physician / Caution: US Federal law restricts this device to sale by or on the order of a physician / Caution: US Federal law restricts this device to sale by or on the order of a physician
	Indicates the date after which the medical device is not to be used / Indicates the date after which the medical device is not to be used / Indicates the date after which the medical device is not to be used / Indicates the date after which the medical device is not to be used / Indicates the date after which the medical device is not to be used
STERILE EO	Indicates a medical device that has been sterilized using ethylene oxide / Indicates a medical device that has been sterilized using ethylene oxide / Indicates a medical device that has been sterilized using ethylene oxide / Indicates a medical device that has been sterilized using ethylene oxide / Indicates a medical device that has been sterilized using ethylene oxide
STERILIZE	Indicates a medical device that is not to be re-sterilized / Indicates a medical device that is not to be re-sterilized / Indicates a medical device that is not to be re-sterilized / Indicates a medical device that is not to be re-sterilized / Indicates a medical device that is not to be re-sterilized
	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information / Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information / Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information / Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information / Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Indicates a medical device that is intended for one single use only / Indicates a medical device that is intended for one single use only / Indicates a medical device that is intended for one single use only / Indicates a medical device that is intended for one single use only / Indicates a medical device that is intended for one single use only
	Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself / Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself / Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself / Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself / Indicates the need for the user to consult the instructions for use for important, cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
i	Indicates the need for the user to consult the instructions for use / Indicates the need for the user to consult the instructions for use / Indicates the need for the user to consult the instructions for use / Indicates the need for the user to consult the instructions for use / Indicates the need for the user to consult the instructions for use
	Indicates Medical Device Manufacturer / Indicates Medical Device Manufacturer / Indicates Medical Device Manufacturer / Indicates Medical Device Manufacturer / Indicates Medical Device Manufacturer
GB	To identify the country of manufacture of products (Made in the United Kingdom) / To identify the country of manufacture of products (Made in the United Kingdom) / To identify the country of manufacture of products (Made in the United Kingdom) / To identify the country of manufacture of products (Made in the United Kingdom) / To identify the country of manufacture of products (Made in the United Kingdom)
QTY	Indicates the packaged quantity / Indicates the packaged quantity / Indicates the packaged quantity / Indicates the packaged quantity / Indicates the packaged quantity
	Indicates the entity distributing the medical device into the locale / Indicates the entity distributing the medical device into the locale / Indicates the entity distributing the medical device into the locale / Indicates the entity distributing the medical device into the locale / Indicates the entity distributing the medical device into the locale
MD	Indicates the item is a medical device / Indicates the item is a medical device / Indicates the item is a medical device / Indicates the item is a medical device / Indicates the item is a medical device
UDI	Indicates a carrier that contains Unique Device Identifier Information / Indicates a carrier that contains Unique Device Identifier Information / Indicates a carrier that contains Unique Device Identifier Information / Indicates a carrier that contains Unique Device Identifier Information / Indicates a carrier that contains Unique Device Identifier Information
CE 2797	Indicates that the product conforms to EU Regulation 2017/745 and meets applicable health, safety and environmental requirements. if the mark is accompanied by a number, conformity is verified / Indicates that the product conforms to EU Regulation 2017/745 and meets applicable health, safety and environmental requirements. if the mark is accompanied by a number, conformity is verified / Indicates that the product conforms to EU Regulation 2017/745 and meets applicable health, safety and environmental requirements. if the mark is accompanied by a number, conformity is verified / Indicates that the product conforms to EU Regulation 2017/745 and meets applicable health, safety and environmental requirements. if the mark is accompanied by a number, conformity is verified / Indicates that the product conforms to EU Regulation 2017/745 and meets applicable health, safety and environmental requirements. if the mark is accompanied by a number, conformity is verified
UK CA 0086	Indicates that a product conforms to the Medical Device Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 202 (SI 1478) and meets applicable health, safety, and environmental requirements. If the mark is accompanied by a number, conformity is verified. / Indicates that a product conforms to the Medical Device Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 202 (SI 1478) and meets applicable health, safety, and environmental requirements. If the mark is accompanied by a number, conformity is verified. / Indicates that a product conforms to the Medical Device Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 202 (SI 1478) and meets applicable health, safety, and environmental requirements. If the mark is accompanied by a number, conformity is verified. / Indicates that a product conforms to the Medical Device Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 202 (SI 1478) and meets applicable health, safety, and environmental requirements. If the mark is accompanied by a number, conformity is verified. / Indicates that a product conforms to the Medical Device Regulations 2002 (SI 618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 202 (SI 1478) and meets applicable health, safety, and environmental requirements. If the mark is accompanied by a number, conformity is verified.

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