

# RETRACTORS

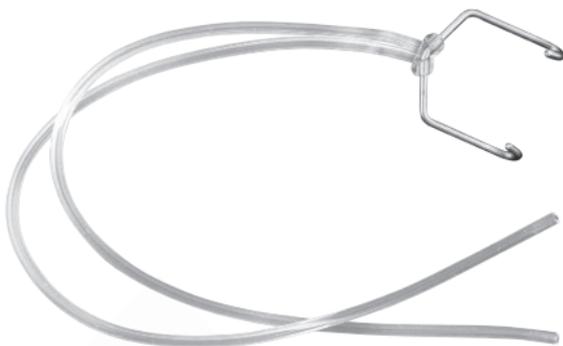
## Instructions for Use

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### REF

FHR0510, GDR2001, MFR0410

MFR0410 –  
**Maxillofacial Retractor**



FHR0510 –  
**Fish Hook Retractor**

GDR2001 –  
**Grooved Director**





## DESCRIPTION

Retractors can be used to retract and stabilise soft tissue and skin during procedures.

## MATERIALS OF CONSTRUCTION

Product Component	Details
FHR0510	302 S26 Stainless Steel hook with an attached silicone tube
GDR2001	430 Stainless Steel
MFR0410	302 S26 Stainless Steel hook with an attached silicone tube

## INTENDED USE

The Fish Hook and Maxillofacial Retractors are intended for retracting skin during surgical procedures.

The Grooved Directors are dual ended devices used to probe, stabilise and retract soft tissue.

## INTENDED USER

The device is intended to be used by appropriately trained healthcare professionals.

## INDICATIONS, CONTRAINDICATIONS AND PATIENT SELECTION FACTORS

The Fish Hook and Maxillofacial Retractors are indicated for retracting skin during surgical procedures.

The Grooved Directors are indicated for use in the probing, stabilisation and retraction of soft tissue.

These devices are made of Stainless Steel, which may cause an allergic reaction in patients with sensitivity to Nickel. User should risk assess the use of the device in relation to the medical benefit of the procedure and take necessary precautions with patients with known sensitivity to Nickel.

The Fish Hook and Maxillofacial Retractors are made of silicone which may cause an allergic reaction in patients with sensitivity to this material. User should risk assess the use of the device in relation to the medical benefit of the procedure and take necessary precautions with patients with known sensitivity to silicone.

Do not use with in direct contact with the heart, central circulatory (arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior) and central nervous system (brain, meninges and spinal cord).

## **PATIENT POPULATION**

Fish Hook and Maxillofacial Retractors: Anyone of any age in the human population as determined by a suitably qualified surgeon.

Grooved Directors: Anyone of any age in the human population as determined by a suitably qualified healthcare professional.

## **WARNINGS AND PRECAUTIONS**

This device is supplied STERILE and ready to use.

The device is for SINGLE USE ONLY. Do NOT re-sterilise or re-use.

Do not use if the packaging has been opened or damaged.

If the device accidentally becomes contaminated before use, do not use and dispose of accordingly.

The Fish Hook and Maxillofacial Retractors are sharp. Caution should be exercised at all times when handling and using these devices.

## **SHELF LIFE AND STERILITY**

The instruments are sterilised by exposure to Ethylene Oxide, as indicated by the symbol on the label. They remain sterile as long as the package integrity has not been compromised.

The expiration date is printed on the label. Do not use instruments after the expiration date. The shelf life is 5 years.

Devices are single use, transient devices. Therefore, the device lifetime in use is less than 60 minutes continuous use.

## **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 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**

The Fish Hook and Maxillofacial retractors hook the skin and retraction is established by tensioning the silicone tube to hold the skin and hook in place.

The Grooved Directors are standard devices, for operational use please refer to the indications and intended use.

## **DEVICE DISPOSAL**

After use, the device should be disposed of in accordance with the healthcare settings disposal procedure. The product comes into contact with bodily fluids, which can be contaminated. Care should be taken in the handling and disposal of the device after use to prevent contamination.

Retractors are sharp and must be placed in a secure puncture-resistant bin (conforming to appropriate regulations) which is suitable for incineration.

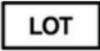
The products do not contain:

- 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

## **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](http://www.dtrmedical.com/contact) and the competent authority, ministry of health, or delegated agency in which the suspected serious incident has occurred.

<b>SYMBOL REFERENCE TABLE</b>	
	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the date after which the medical device is not to be used.
	Sterilised using Ethylene Oxide.
	Indicates a medical device that is not to be re-sterilised.
	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 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.
	Indicates Medical Device Manufacturer.
	To identify the country of manufacture of products (Made in the United Kingdom).
	Indicates the packaged quantity.

<b>SYMBOL REFERENCE TABLE</b>	
	Indicates the item is a medical device.
	Indicates a carrier that contains Unique Device Identifier Information.
	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 the entity distributing the medical device into the locale
	Keep away from sunlight.
	Keep dry.
	Caution: US Federal law restricts this device to sale by or on the order of a physician



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