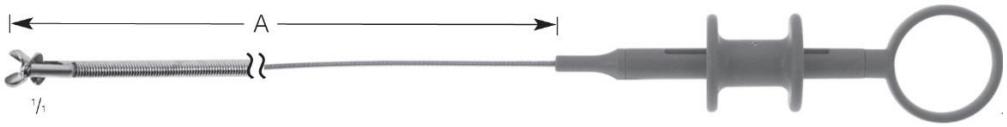
Disposable Myocardium Biopsy Forceps, sterile
REF: MOA-1 ..-9, MOB-1

℞ only

CAUTION: U. S. A Federal law restricts this device to sale by or on the order of a physician

This instruction does not substitute reading the instructions for use of the employed accessories.

DEVICE DESCRIPTION



Length of shaft "A"	1,6 mm	1,8 mm	2,2 mm
510 mm	MOA-1	MOA-5	MOA-9
800 mm	MOA-2	MOA-6	–
1000 mm	MOA-3	MOA-7	–
1200 mm	MOA-4	MOA-8	MOB-1

The biopsy forceps are designed to allow percutaneous access to the right or left ventricles of the heart in order to obtain diagnostic tissue samples. At the distal end of the forceps is a pair of stainless steel jaws used to obtain the heart tissue samples. At the proximately end of the forceps is the actuation handle used to activate the jaws and steer the device.

WARNINGS AND PRECAUTIONS

Single use, Do not process - do not reuse!
Dispose of the biopsy forceps according to the regulations in the collecting box for used disposable products in the operation theatre.

Do not use products from damaged packaging and return them to the manufacturer!
Do not use products whose expiration date has passed! Risk of infection!

Use only perfect and sterilized products!
Always handle biopsy forceps with care! Risk of damage → Risk of injury!

Do not store under +5°C and over +40°C for prolonged periods!
Observe expiration date! Do not use after expiration date!

The biopsy forceps shall only be used by cardiologists or heart surgeons with support by personnel with special training and if indicated and if there are no contraindications.

Myocardium biopsy forceps shall only be used and disposed of by competent medical personnel!

The procedure must be performed under radiographic control in order to reliably move the distal end of the instrument into the ventricle. – Failure to do so may result in injury!

Biopsy forceps are precise mechanical products. Please always handle with care! Risk of damage! Risk of injury!

For pre-shaping the distal part, place it on both thumbs and then use the index fingers to bend the shaft across the two thumbs! Do not kink! Risk of immobility → Risk of injury!

Do not bring any load on the connection area of shaft and function (distal) end – Risk of breakage → Risk of injury!

After taking the sample, make sure to keep the spoons of the biopsy forceps closed until the biopsy forceps have been removed from the body and the sample shall be recovered. → Risk of embolism if the specimen is lost!

INTENDED USE:

FEHLING biopsy forceps are used to obtain endomyocardial biopsy specimens from the right and left ventricle via percutaneous arterial or venous approach.

CONTRAINDICATIONS

- Secondary involvement in systemic diseases such as sarcoidosis, amyloidosis or hemochromatosis
- Neoplasia: e.g. myxoma, rhabdomyoma, sarcoma or metastases
- Cardioneuropathy: e.g. progressive muscular dystrophy
- Toxic cardiomyopathy: e.g. due to cytostatics
- Cardiac tumors
- Coronary heart disease
- Mechanical valve replacement of the heart valve through which the forceps are to be passed

POSSIBLE ADVERSE EFFECTS OF ENDOMYOCARDIAL BIOPSY (EMB)

In the medical literature, the following adverse effects are described for endomyocardial biopsy (EMB) that can also occur during the intended use of FEHLING biopsy forceps:

- Right ventricular perforation
- Pericardial tamponade
- Polarization and conduction disorders
- Persistent bleeding from the vessel puncture site
- Arrhythmia
- Vasovagal response
- Allergic reactions
- Neurological complications (due to embolization of calcifications in vessels through which the forceps are advanced)
- Tricuspid valve regurgitation resulting from frequently repeated endomyocardial biopsies (only in cardiac transplant patients)

As for adults, the decision to perform an EMB in children can only be made by the attending physician after considering all the benefits and risks.

DIRECTIONS FOR USE

The procedure is similar to that of a conventional cardiac catheter examination; usually endomyocardial biopsies are executed within the scope of a cardiac catheter examination that was performed anyway, in the cardiac catheter laboratory. For the rejection diagnosis the endomyocardial biopsy from the right ventricle has proven to be the method of choice.

1	Check sterility and packaging for integrity! Using products from damaged packaging is associated with the risk of infection!

	Do not use products from damaged packaging and return them to the manufacturer! Do not use products whose expiration date has passed! Risk of infection!
2	Check function of biopsy forceps by opening and closing several times!
3	Visually inspect biopsy forceps for sharp edges and damage!
4	Use only perfect and sterilized products!
5	Choose appropriate introducer sheaths We recommend using the introducer sheaths for the jaw diameters sizes listed:

Jaw	Introducer sheath inner Ø
1,6 mm	5 F
1,8 mm	6 F
2,2 mm	7 F
2,2 mm	8 F

6	The procedure must be performed under radiographic control in order for the distal end of the instrument to be taken to the removal site reliably. Failure to do so may result in injury.
7	To enable the access of the cutting end of the biopsy forceps to any location of the ventricle, bend the distal 20 – 50 mm area.
	⚠ Do not bring any load on the connection area of shaft and function (distal) end – Risk of breakage → Risk of injury!
	⚠ For pre-shaping the distal part, place it on both thumbs and then use the index fingers to bend the shaft across the two thumbs! Do not kink! Risk of immobility → Risk of injury!

	RIGHT VENTRICULAR BIOPSY	LEFT VENTRICULAR BIOPSY
8	Once disinfection and local anesthesia of the puncture location is performed, a sheath is introduced in the vein (femoral vein, jugular vein) according to Seldinger.	Once disinfection and local anesthesia of the puncture location is performed, a sheath is introduced in the artery (femoral artery) according to Seldinger.
9	Close spoon by relaxing the handle components, then insert the biopsy forceps through the venous system into the ventricle	Close spoon by relaxing the handle components, then insert the biopsy forceps through the artery system into the ventricle
	⚠ Risk of injury to the vessel walls if spoons are open! Advance the biopsy forceps into the working channel slowly, carefully and without any use of force. Do not kink! → Risk of injury!	
10	Move forward through the vena cava with a biopsy forceps to the level of the right atrium, pass through the tricuspid valve and take samples from the ventricle walls.	Move forward through the aorta with a biopsy forceps, pass through the aortic valve and take samples from the ventricle walls.

11	After taking the sample, make sure to keep the spoons of the biopsy forceps closed until the biopsy forceps have been removed from the body and the sample shall be recovered. → Risk of embolism if the specimen is lost! Removal of forceps should be performed immediately after each sample taking.
12	This procedure can take 15 – 30 minutes and in exceptional cases, it can take longer. After the procedure, apply pressure to the puncture location to prevent bleeding and cover the site with a dressing.

AFTER USE:

	Dispose of the biopsy forceps according to the regulations in the collecting box for used disposable products in the operation theatre. Do not process, do not reuse! – Disposable product – risk of infection!

STORAGE

	Do not store under +5°C and over +40°C for prolonged periods! Observe expiration date! Do not use after expiration date!

USED SYMBOLS:

			CE 0297	REF	LOT
Single use - Not to be reused	Consult instructions for use	Caution! See warning and precautions!	Notified Body	Reference number	Batch number
STERILE EO					
Sterilisation by Ethylene oxide	Do not use damaged package	Store in a dry place!	Protect from excessive heat!	Manufacturer	Use before

! Each modification to the product or deviation from these instructions of use results in exclusion of liability!

Subject to change without notice.

Contact to manufacturer:

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