



Disposable Myocardium Biopsy Forceps, sterile REF: MOA-1 ..-9, MOB-1, MOB-4, MOB-5



Single use, do not reuse!



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!

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

Intended use:

FEHLING biopsy forceps are specified for the taking of tissue samples for the examination of fine tissue, specifically endomyocardial biopsy.

Indications and contraindications for endomyocardial biopsy

The endomyocardial biopsy, also designated as "biopsy" in everyday usage, is the taking of a myocardial sample for the examination of fine tissue. The objective of this examination is to determine the cause of independent myocardiosis that have not been caused by hypertension, coronary artery diseases or heart defects, monitoring of the progression of such a disease or after heart transplantation (rejection diagnosis).

On a global scale, the most common application of endomyocardial biopsy is in the diagnosis of rejection responses after heart transplantations.

The diagnostic benefit of endomyocardial biopsy has strongly increased over the last decades through the introduction of new techniques in biomolecular, immunological and virological fields and the related enhancement of the diagnostic and differential diagnostic possibilities of inflammatory myocardial diseases, because the endomyocardial biopsy can serve to confirm these diagnoses.

Indications

- Diagnosing inflammatory cardiomyopathy, follow-up and differential diagnostics.
- Suspected inflammatory cardiovascular pathogenesis.
- Existing dilated cardiomyopathy (to exclude myocarditis).
- Differential diagnostics: confirmation or exclusion of myocardial involvement, e.g. in the context of a systemic disease.

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 / arterial puncture / AV fistulas
- Pericardial tamponade
- Polarization and conduction disorders
- Persistent bleeding from the vessel puncture site, local haematoma / pseudoaneurysms
- 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)
- Hypotension/hypertension, chest pains, dyspnoea

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.

Before use:



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!



Check function of biopsy forceps by opening and closing several times!
Visually inspect biopsy forceps for sharp edges and damage!
Use only perfect and sterilized products!
Biopsy forceps are fine-mechanical products. Please always handle with care! Risk of damage → Risk of injury!

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



During 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



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.

After disinfection and local anesthesia of the puncture location, a sheath is introduced in the vein (right ventricular biopsy - femoral vein, jugular vein) or in the artery (left ventricular biopsy - femoral artery) according to Seldinger.

For the rejection diagnosis the endomyocardial biopsy from the right ventricle has proven to be the method of choice. After disinfection and local anesthesia of the puncture location, the technique consists of puncturing the right jugular vein or femoral vein in which a sheath according to Seldinger is placed. You then move down the vena cava with a biopsy forceps to the level of the right atrium, pass through the tricuspid valve and take samples from the interventricular septum.



Only bend the distal part of the shaft forward in the area from 25 to 50 mm distal!
Keep a minimum radius of 12 – 15 mm.

To bend the shaft forward, 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 subject the connection area between the shaft and the articulated arms to bending stresses – Risk of breakage → Risk of injury!



Only insert the biopsy forceps through the vessel system into the ventricle with the spoon closed, i.e. with relaxed handle parts! → 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!



After the procedure, remove the biopsy forceps from the working channel immediately.

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 can be recovered. → Risk of embolism if the specimen is lost!

This procedure can take 15 – 30 minutes and in exceptional cases, can also 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:					
Single use - Not to be reused	Observe instruc- tions for use	Attention!	Use before	Reference number	Batch number
Sterilisation by Ethylene oxide	Do not use dam- aged package	Store in dry place!	Protect from excessive heat!	Notified Body	

! 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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