

Instructions for use – Cups & Pins

REF 4011EU – Cups & Pins

UDI 59998629924011EU_1UU

Intended purpose

  **The Cups & Pins are single use specimen receptacles for professional use, intended for viscoelastometry analysis of citrated blood samples.**



CAUTION: A use of the device outside of its intended purpose, may lead to the test results being incorrectly interpreted by the user.

Indications for use

Indicated to be used for the performance of viscoelastometry analysis.

Contra-indications for use

As the device is a receptacle for viscoelastometry analysis, no limitations on its use are introduced. The contra-indications of the performed assay apply.

Intended users



- trained healthcare professionals,
- trained laboratory professionals.

Environment of use

Indoors in a typical setting of a laboratory, equipped and designed to ensure standard electrical connections, adequate lighting as well as standard environment settings regarding temperature, humidity and pressure to ensure the functionality of typical electrical devices like electrical medical devices and personal computers.

Intended patient population

As the device is a receptacle for viscoelastometry analysis, no limitations on its use are introduced. The limitations of the performed assay apply.

Principle of the method

Viscoelastometry [1-2] allows for the detection of whole blood formation in whole blood, and thus detects coagulation initiation (by the clotting time, CT), blood clot firmness (by the maximum clot

firmness, MCF, or related parameters, such as the A20, amplitude 20 minutes after CT) and clot stability or fibrinolysis (by the maximum lysis, ML).

In viscoelastometry the kinetics of the whole blood clot formation are measured as follows: The blood sample (typically 340 µl) is placed between a cylindrical cup and a cylindrical pin. The viscoelastometry instrument creates a periodic rotation between the cup and the pin by approx. 5°. As long as the blood is fluid this relative movement is maximal. When the blood clots, the blood clot adheres to the surfaces of the cup and the pin and interferes with the relative movement between these surfaces. The reduction of the relative rotation of cup and pin is a measure for the mechanical strength of the blood clot. It is continuously detected by the viscoelastometry instrument and transformed into the clot amplitude, which is expressed in mm for historic reasons. The cup & pin is used in combination with the respective viscoelastometry reagents.

To ensure a good attachment of the blood clot onto the surfaces of cup and pin, the blood-contacting surfaces are coated with a plastic polymer coating. For quality control purposes this coating includes a light silver color.

Materials provided

120 Cup & Pins provided in 6 packages of 20 Cups & Pins each, composed of the plastic Cup and plastic Pin coated with a plastic polymer.

Additional materials and devices required

- Viscoelastometry analyzer
- Electronic pipette
- Viscoelastometry reagents
- Blood collection tube (3.2% sodium citrate) for coagulation testing

Product preparation

The product is ready to use.

Storage and stability

Store at room temperature in the provided primary packaging. The Cups & Pins are stable until the expiration date stated on the label.

Warnings and precautions

For professional use by trained personnel.



CAUTION: Do not use receptacles from defective packaging.



CAUTION: Intended for single use - do not reuse.



CAUTION: Any serious incident that has occurred as a result of the use of the device has to be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CAUTION: Failure to comply with these instructions for use may result in device handling errors leading to wrong test results.



CAUTION: Human blood samples should be handled with care, following general precautions recommended for bio-hazardous materials [3].

CAUTION: General precautions (e.g., wear gloves and minimize skin exposure to specimens and reagents) should be followed when handling all materials.

NOTE: Dispose of waste according to local regulations.

NOTE: A material safety data sheet is available upon request.

Residual risks, undesirable side-effects, and information for the patient

The following residual risks were identified during the risk management activities for the device:

- In case of an off-label use of the product, test results may be incorrectly interpreted by the user.
- In case of device handling errors, patient's coagulation may be incorrectly reflected.
- In case of the use of the expired product, patient's coagulation may be incorrectly reflected.

Warnings and notes are provided throughout the whole instructions for use.

No undesirable side-effects were identified during the post-market activities for the device.

No information for the patient is required to be provided for the device.

Sample collection



CAUTION: Collect a venous blood sample according to the recommended procedures [4-5] using a blood collection tube with 3.2% sodium citrate. Samples should be analyzed within 3 hours from blood collection. Store the blood at room temperature. Always ensure blood collection tubes are filled to the indicated fill volume to avoid excessive citrate levels.

Test procedure

1. Check the expiry date of the device. Expiry date format is yyyy-mm-dd.



CAUTION: Do not use the expired product. The use of the expired product may lead to wrong test results.

2. Create the test in the software of the viscoelastometry analyzer according to the analyzer manual.
3. Open the primary packaging of the Cups & Pins. If necessary, tear the seal (label) open.
4. Remove one Cup & Pin (together). Do not touch the outer surface of the pin!



CAUTION: Do not touch the outer surface of the Pin. Contaminated surface of the pin may lead to wrong test results.

5. Place the Cup and Pin into the analyzer according to the analyzer manual.



CAUTION: Make sure the cup and the pin are completely inserted into the corresponding parts of the analyzer. An incomplete insertion of Cup and / or Pin into their designated places in the analyzer can lead to wrong test results.

6. Add the sample and the reagents to the Cup as described in the instructions for use of the respective assay.
7. Start the test as described in the analyzer manual.
8. The test will stop, or you can stop the test as described in the analyzer manual.
9. Remove the Cup and the Pin and dispose according to local regulations.

Result interpretation and expected values

The viscoelastometry measurements are automatically determined by the analyzer software. Generally, viscoelastometry curves should be smooth and not noisy. For interpretation of the test results, refer to the instructions of use of the respective assay.

Viscoelastometry test results should be interpreted together with other available test results as well as the clinical context of the patient. Consider repeating tests when they are strongly deviating from the clinical context or are otherwise very unexpected.

The comparison of the Cups & Pins provided highly equivalent results to tests using the Cups & Pins by Enicor, Munich, Germany (Deming regression):

Parameter	N	Slope	Intercept
CT	104	0.99	-0.42
A10	96	1.00	-0.05
A20	96	1.00	-0.18
MCF	103	1.01	-0.52
ML	103	1.01	0.13
LT	104	1.00	-2.01

A precision study including 3 operators, 3 instruments and 3 lots of Cups & Pins and 1 lot of reagents (IN assay) with 54 replicates provided the following metrics:

	CT [sec]	A20 [mm]	ML [%]
mean	128.9	57.9	8.6
SD	3.4	0.8	0.6
CV	2.6%	1.4%	7.0%

Limitations and interferences

As the device is a receptacle for viscoelastometry analysis, no limitations and interferences on its use are introduced. The limitations and interferences of the performed assay apply.

Manufacturer



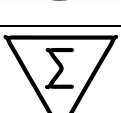
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Symbols

Symbol	Meaning
	Manufacturer
	Batch code
	Country of manufacture
	Consult instructions for use or electronic instructions for use
	Biological risks
	Do not touch pins
	Not intended for near-patient testing
	Unique device identifier

Symbol	Meaning
	Use-by date
	Catalogue number
	Do not use if package is damaged and consult instructions for use
	Do not re-use
	Contains sufficient for <n> tests
	Caution / Warning
	CE marking of conformity
	In vitro diagnostic medical device

References

- [1] Volod O, Bunch CM, Zackariya N, Moore EE, Moore HB, Kwaan HC, Neal MD, Al-Fadhl MD, Patel SS, Wiarda G, Al-Fadhl HD, McCoy ML, Thomas AV, Thomas SG, Gillespie L, Khan RZ, Zamlut M, Kamphues P, Fries D, Walsh MM. Viscoelastic Hemostatic Assays: A Primer on Legacy and New Generation Devices. J Clin Med. 2022 Feb 7;11(3):860.
- [2] Heubner L, Mirus M, Vicent O, Güldner A, Tiebel O, Beyer-Westendorf J, Fries D, Spieth PM. Point of care coagulation management in anesthesiology and critical care. Minerva Anesthesiol. 2022 Jul-Aug;88(7-8):615-628.
- [3] Biosafety in microbiological and biomedical laboratories; U.S. Department of Health and Human Services, Washington, 5th Edition.
- [4] CLSI/NCCLS H03-A6; Procedures for the collection of diagnostic blood specimens by venipuncture.
- [5] CLSI H21-A5 Collection, transport, and processing of blood specimens for testing plasma-based coagulation assays and molecular hemostasis assays.

Version history of these instructions for use

Date	Version	Change description
2025-10-29	1	Initial version