

Percutaneous AVF with the WavelinQ™ EndoAVF System

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BD

Disclosure

Speaker name: Kevin Brundle

I have the following potential conflicts of interest to report:

- Consulting BD Bard
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company



- I do not have any potential conflict of interest

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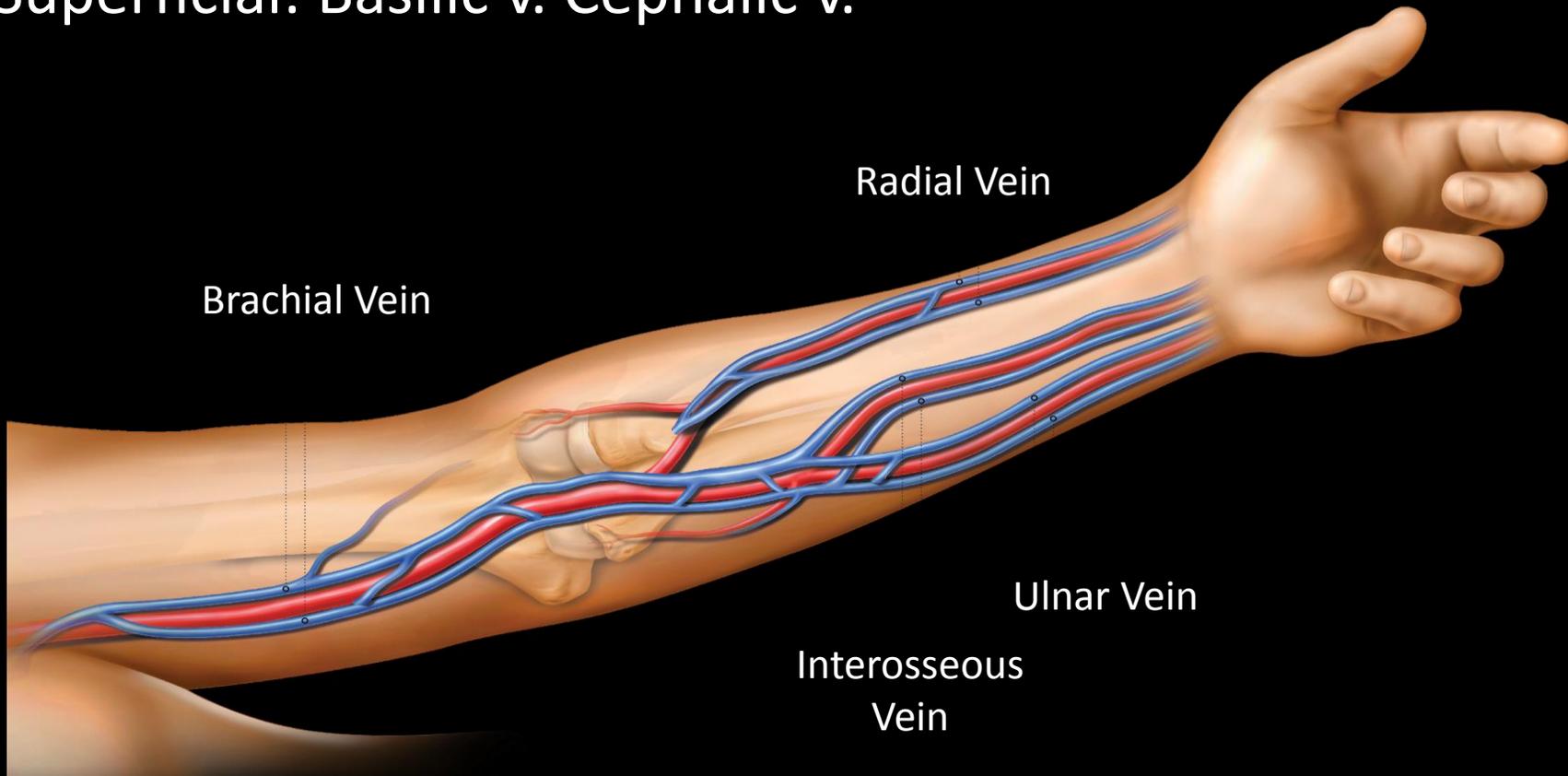
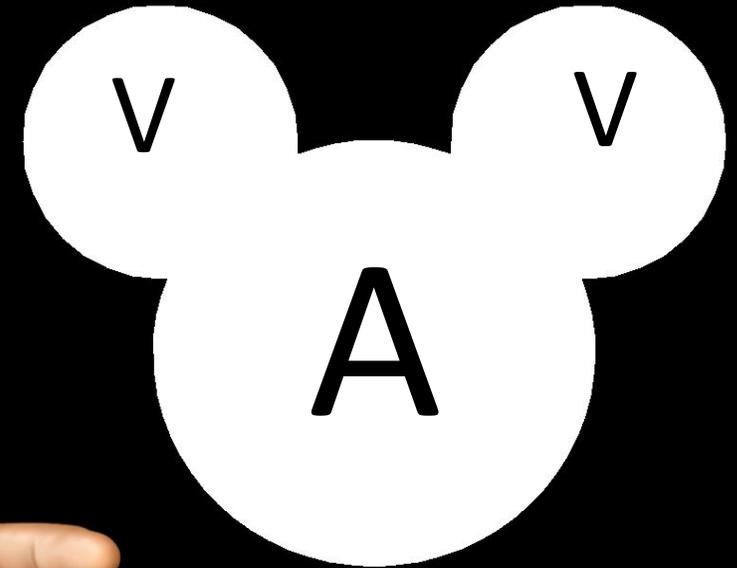
Fundamentals

Two venous networks: Deep and Superficial

One arterial network

Deep Venous + Arterial go together (2:1)

Superficial: Basilic v. Cephalic v.

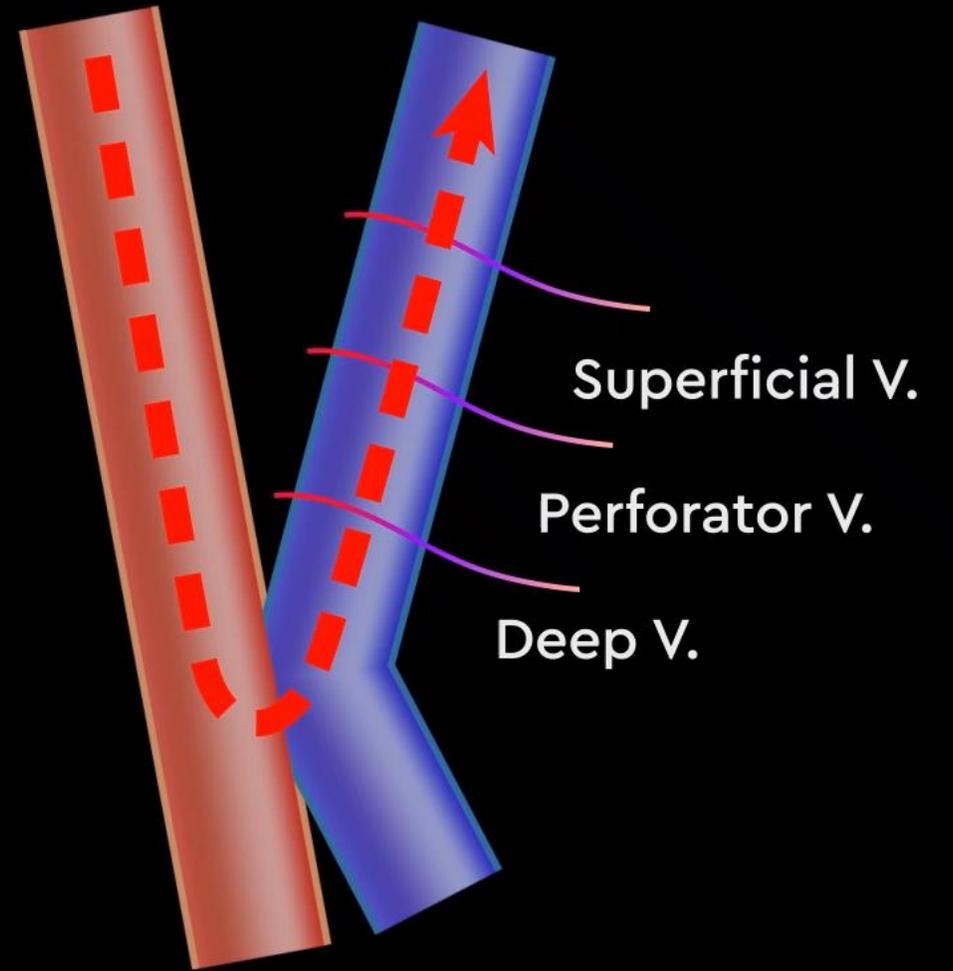


What kind of AVF does WavelinQ™ EndoAVF System create?

Deep Vein AVF

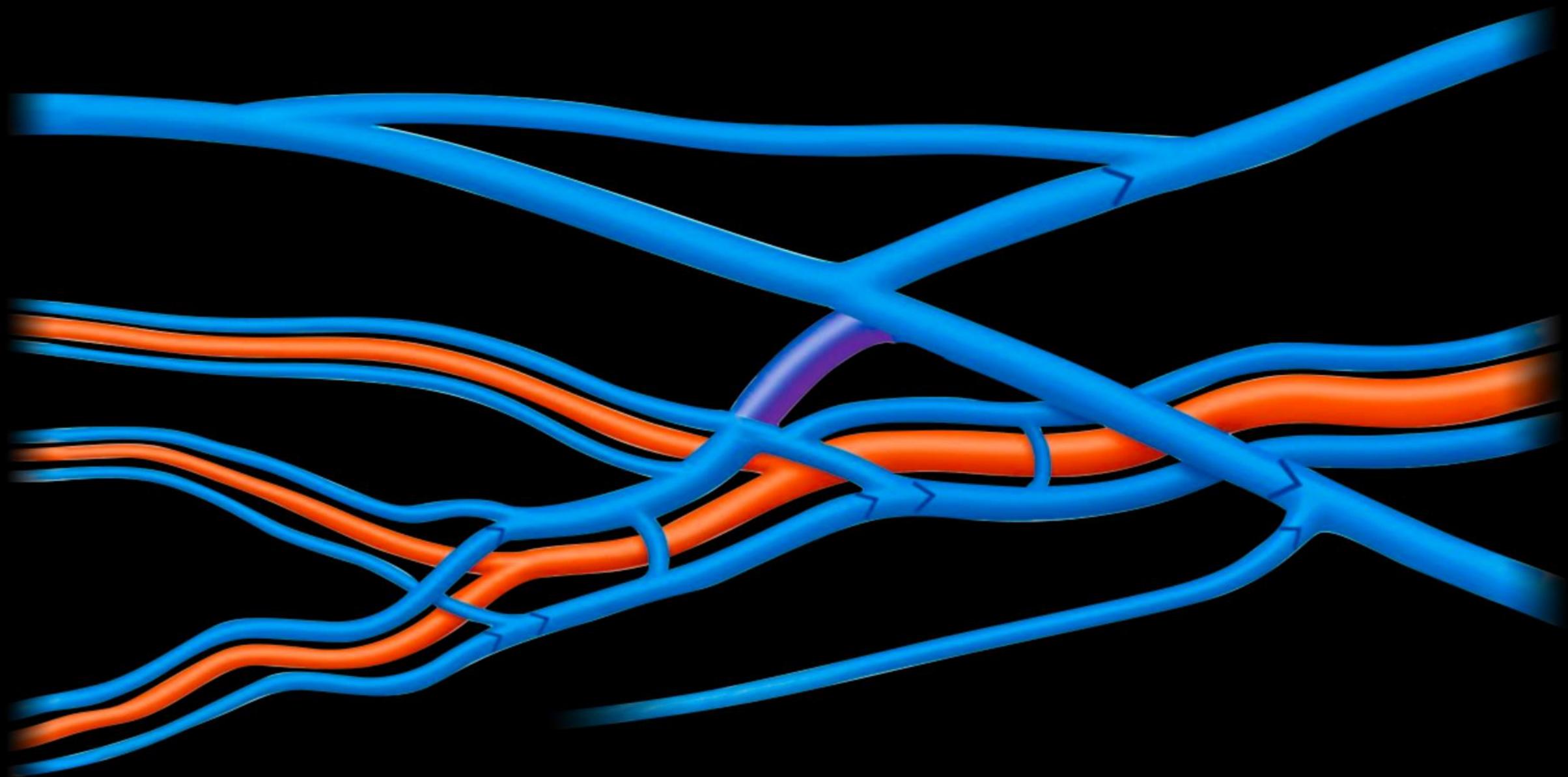
Radial Artery – Radial Vein

Ulnar Artery – Ulnar Vein

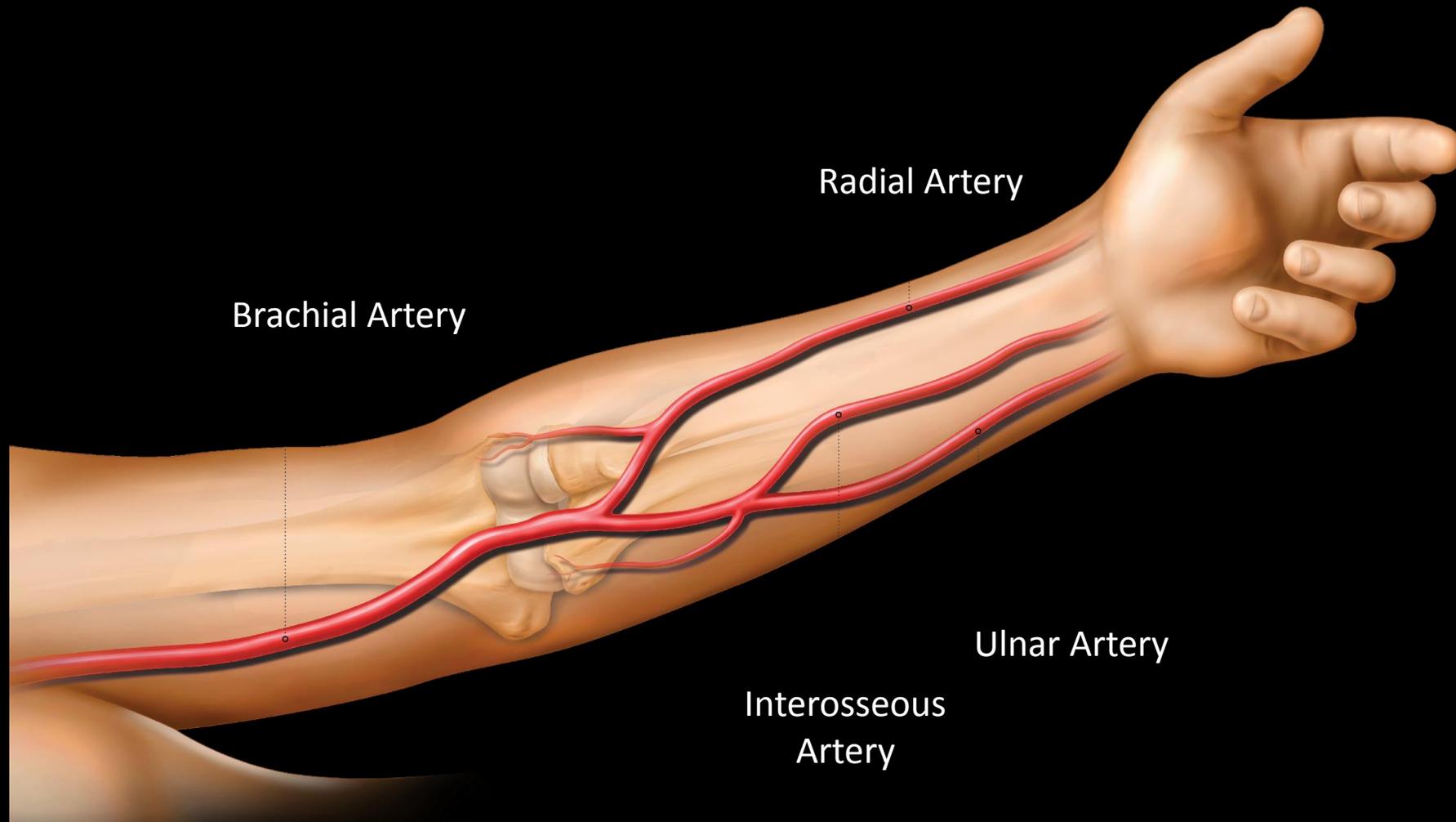


WavelinQ™ EndoAVF System

Planning



Distal Arterial Access - Screening



Calcification



Calcification may inhibit electrode cutting.
Avoid locating the fistula in areas of apparent calcification (DUS/fluoroscopy)

WavelinQ™ EndoAVF System

Venous Catheter



Arterial Catheter

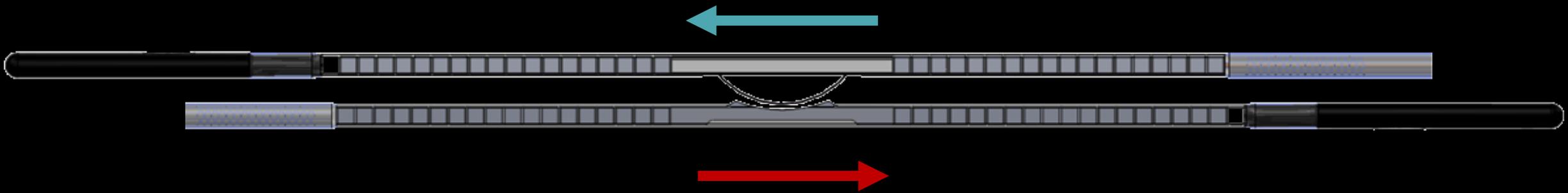
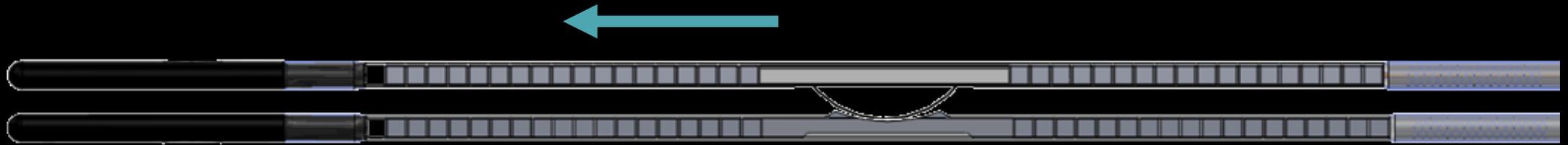
4 Fr catheter profile

Compatible with 5 Fr or 4/5 slender sheath with a .014" guidewire RX

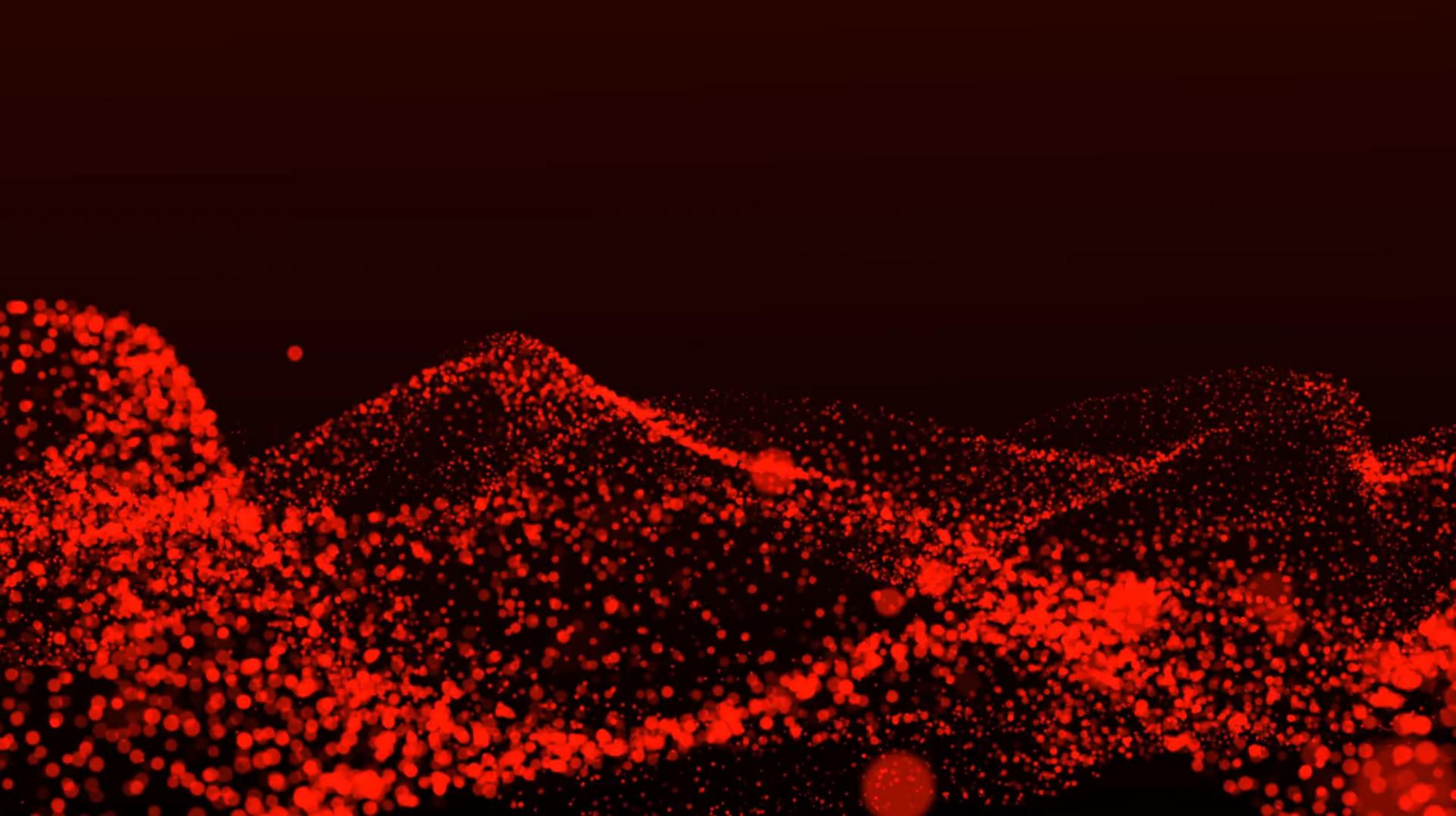
Hydrophilic coating: distal 23 cm

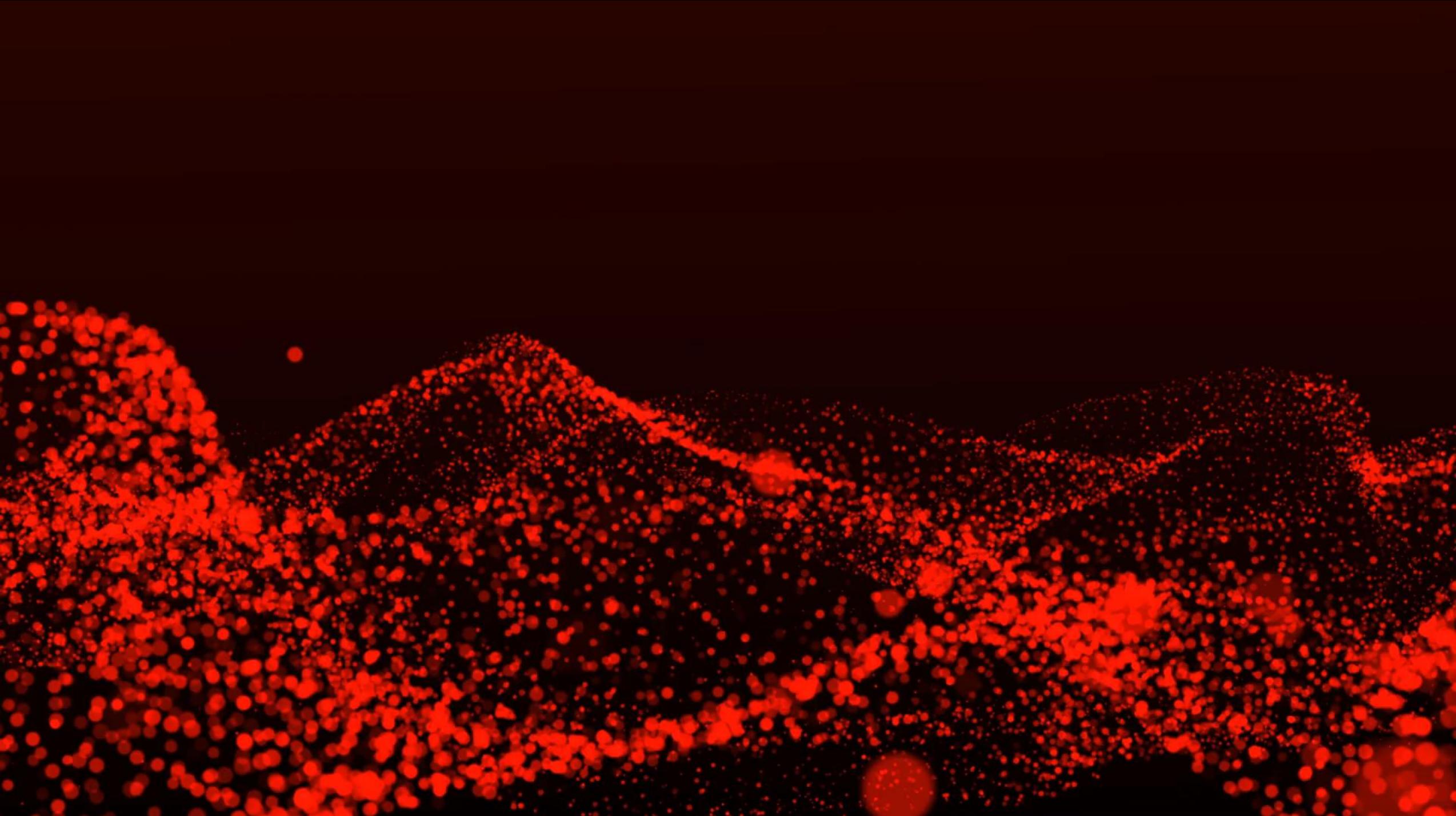
Working length from hub to electrode: 40 cm

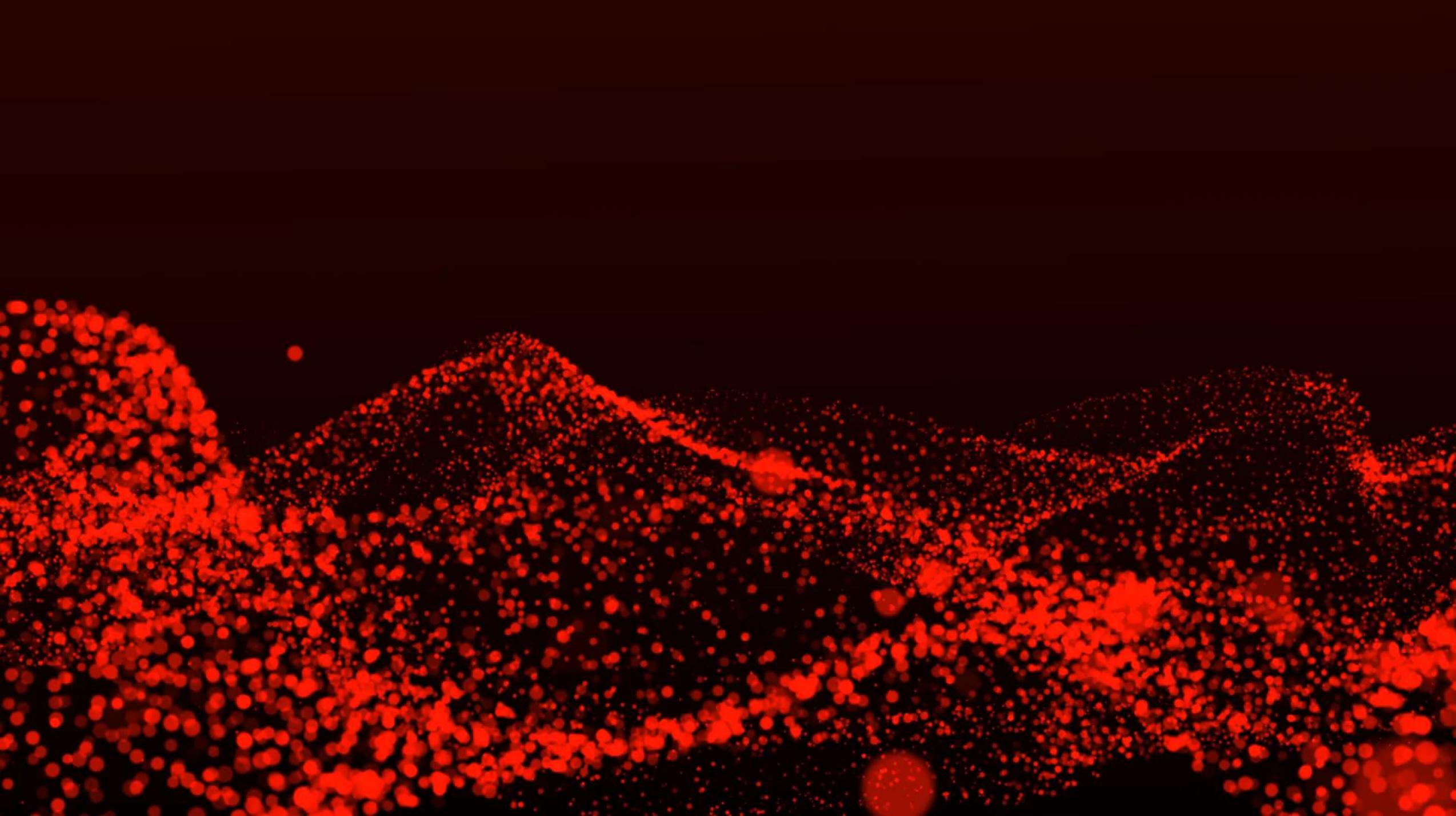
Device Symmetry

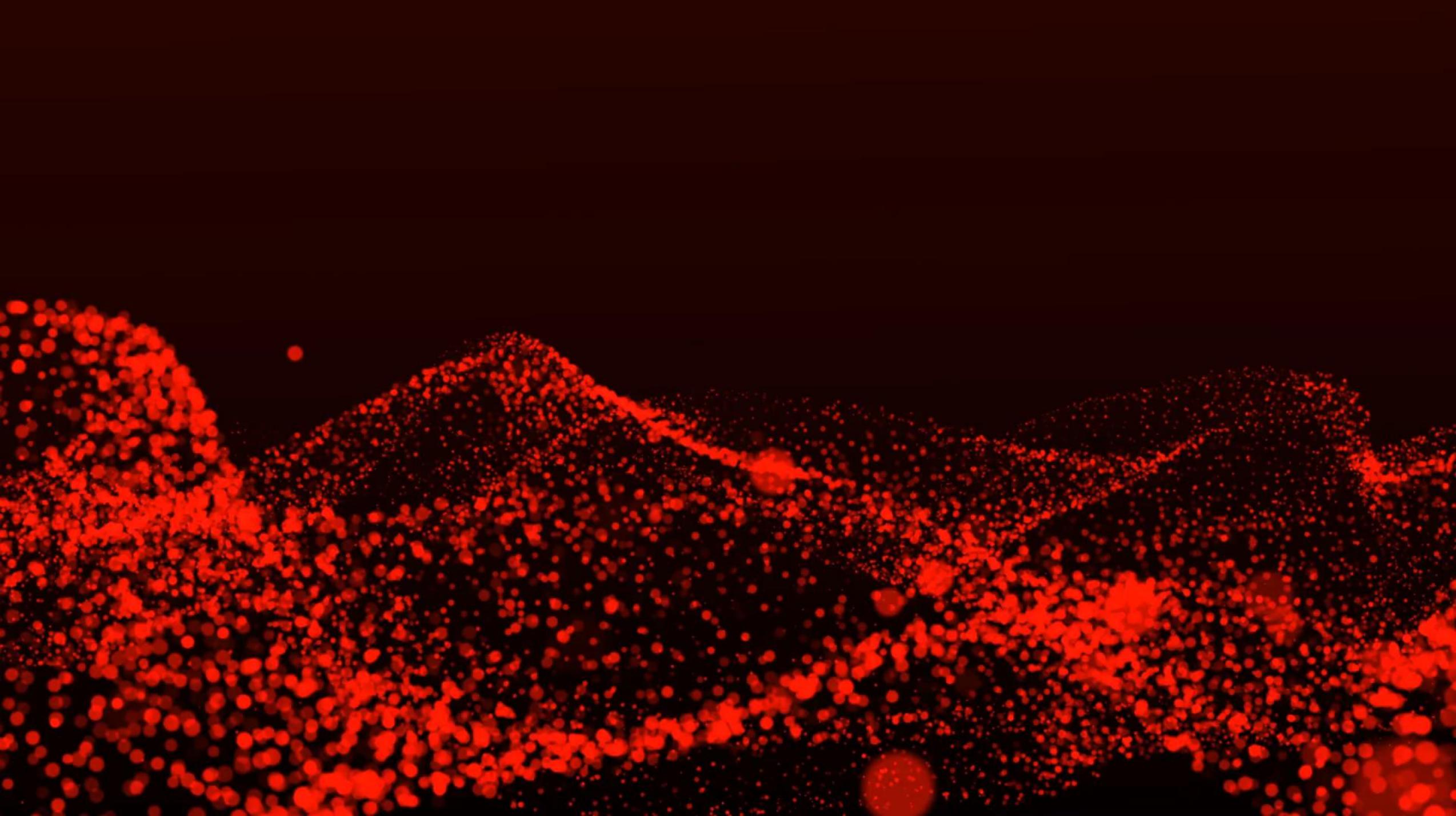


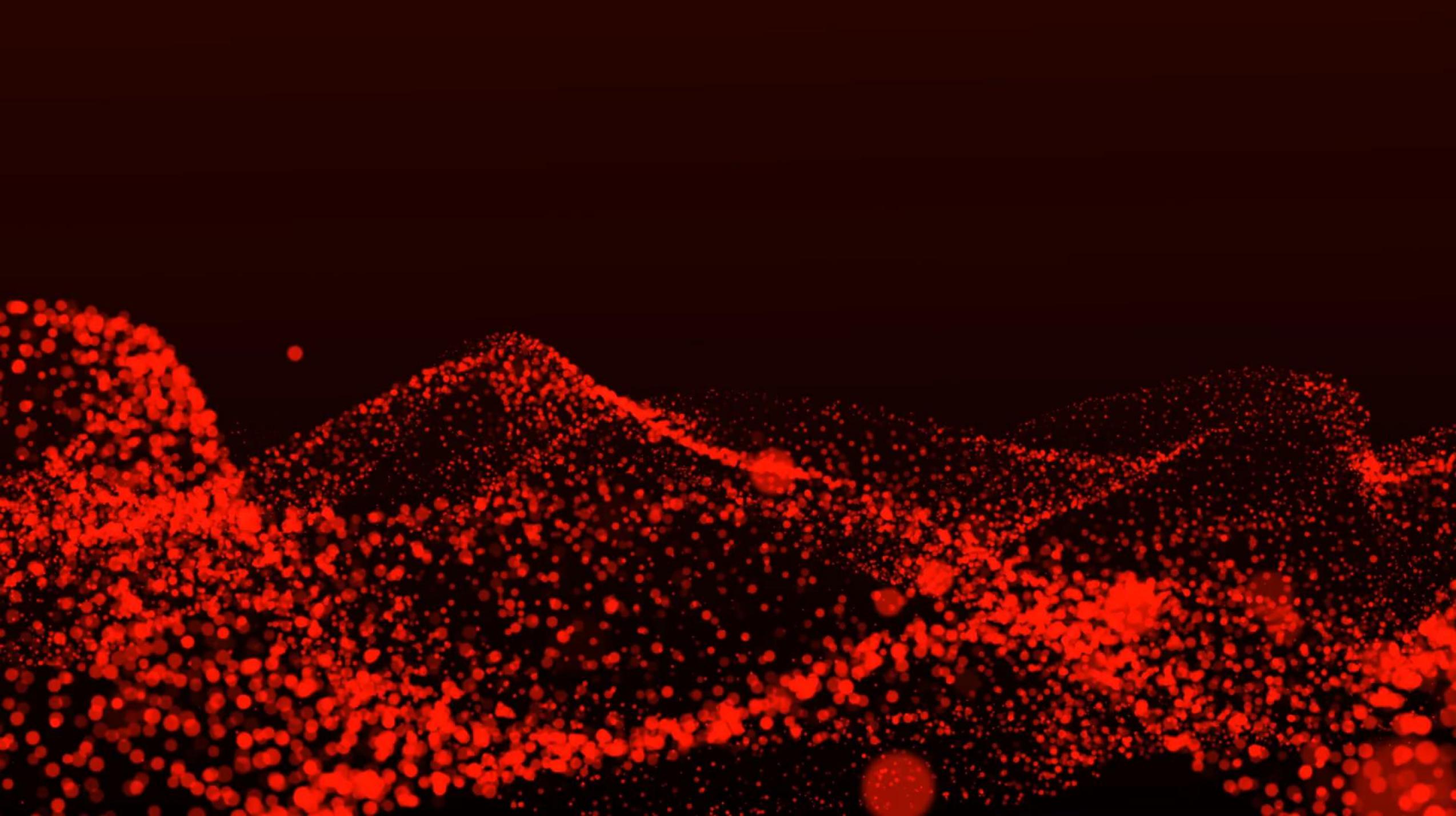
Vessel Mapping

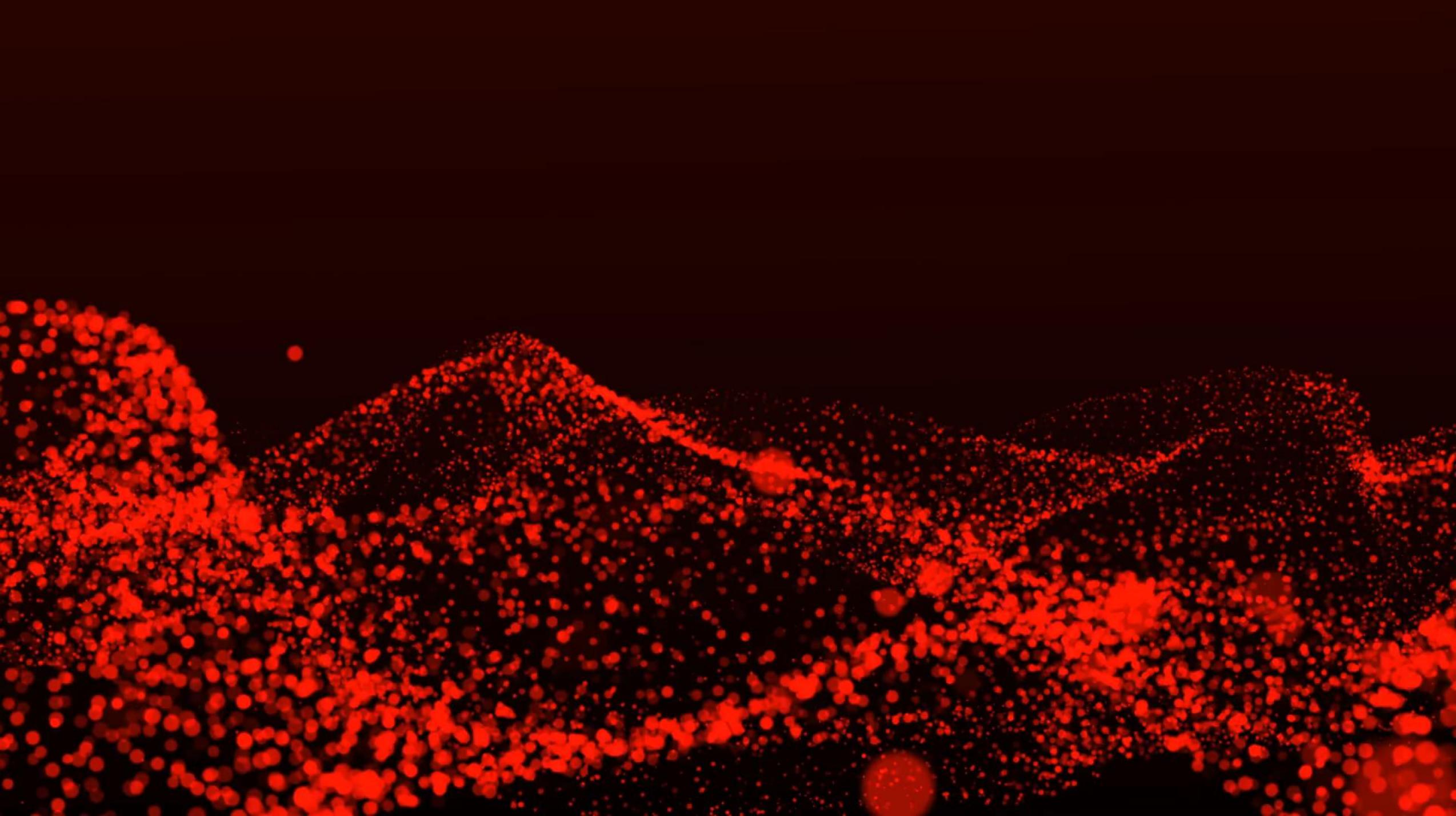


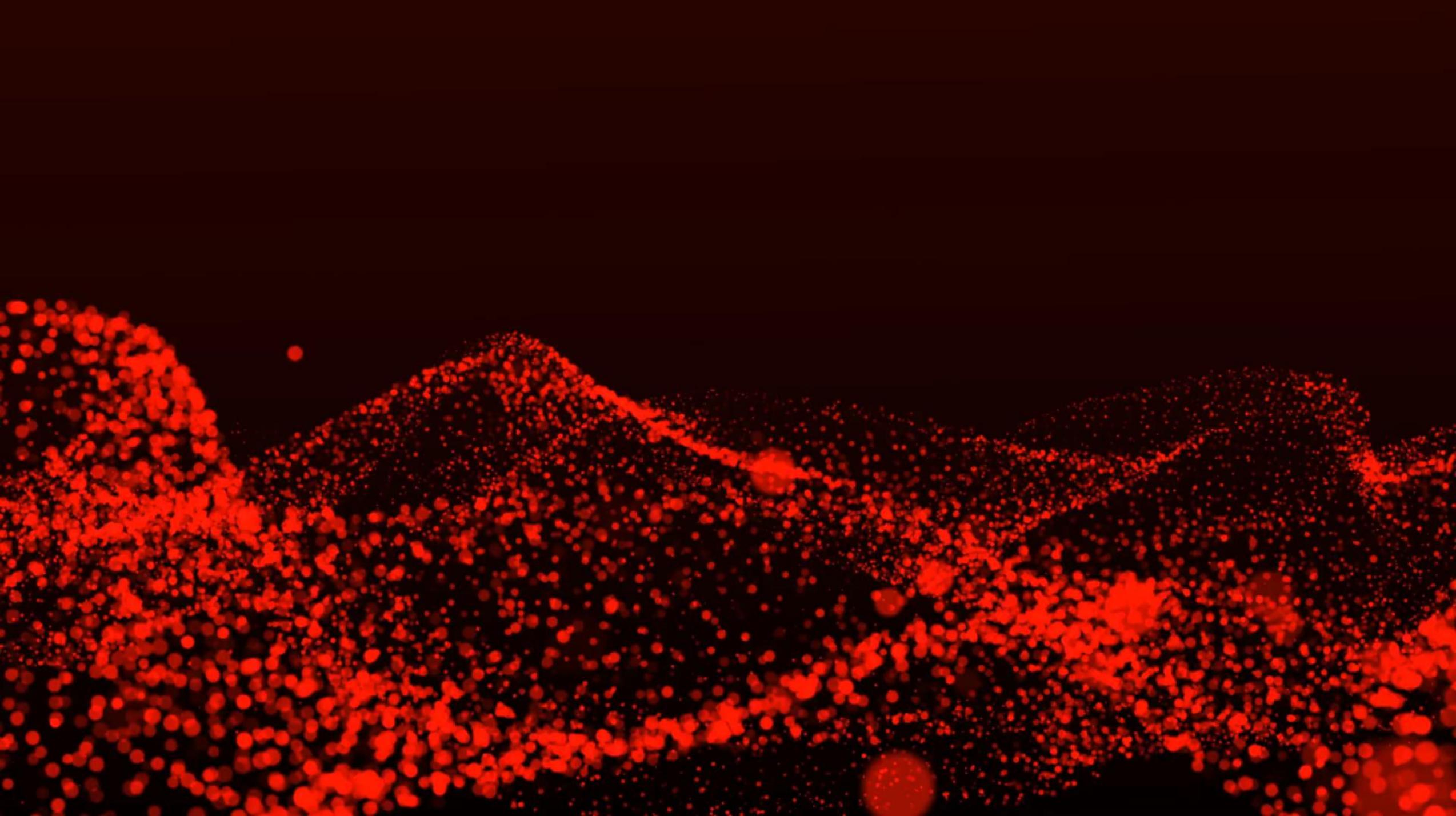












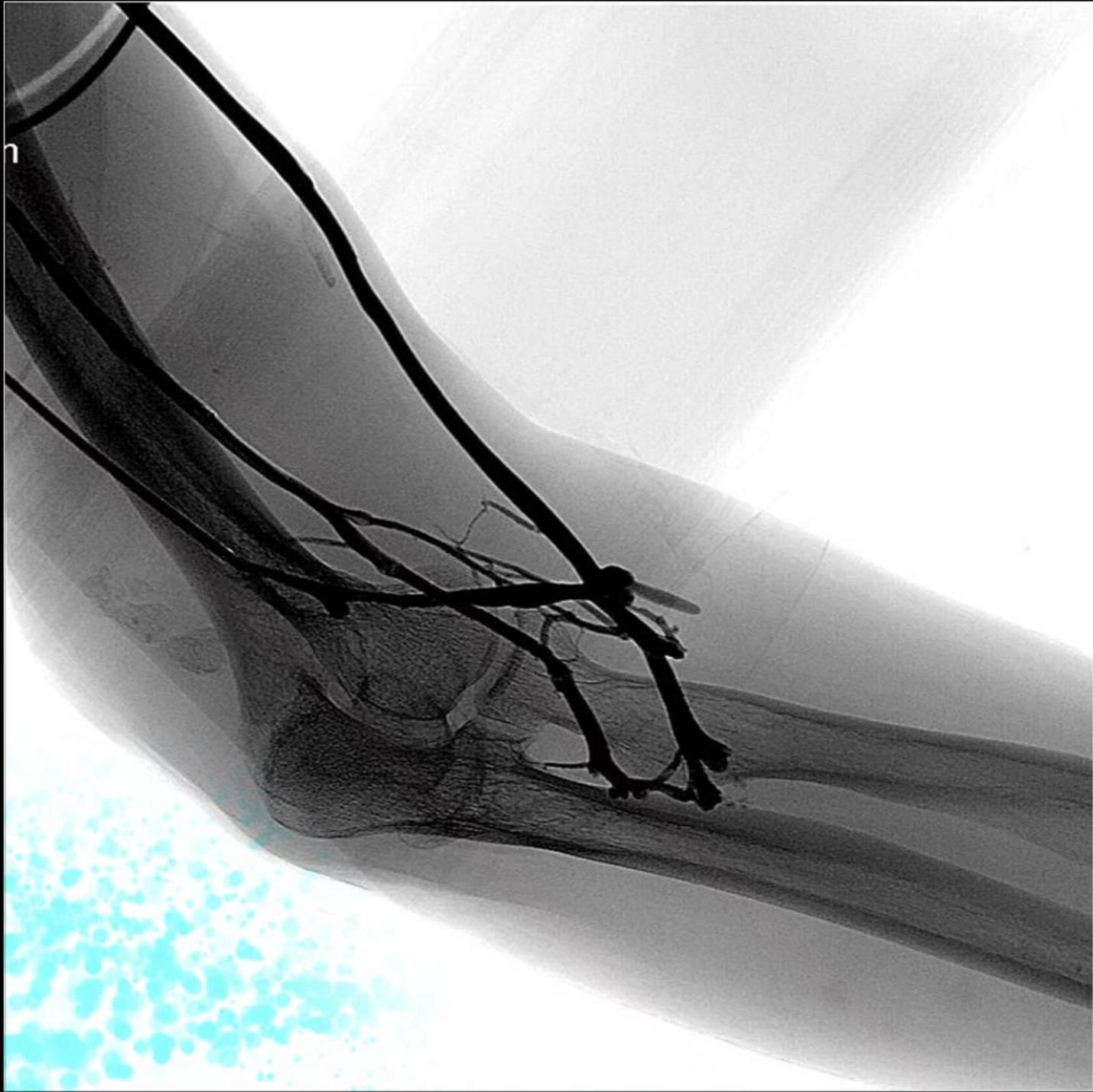
The Procedure



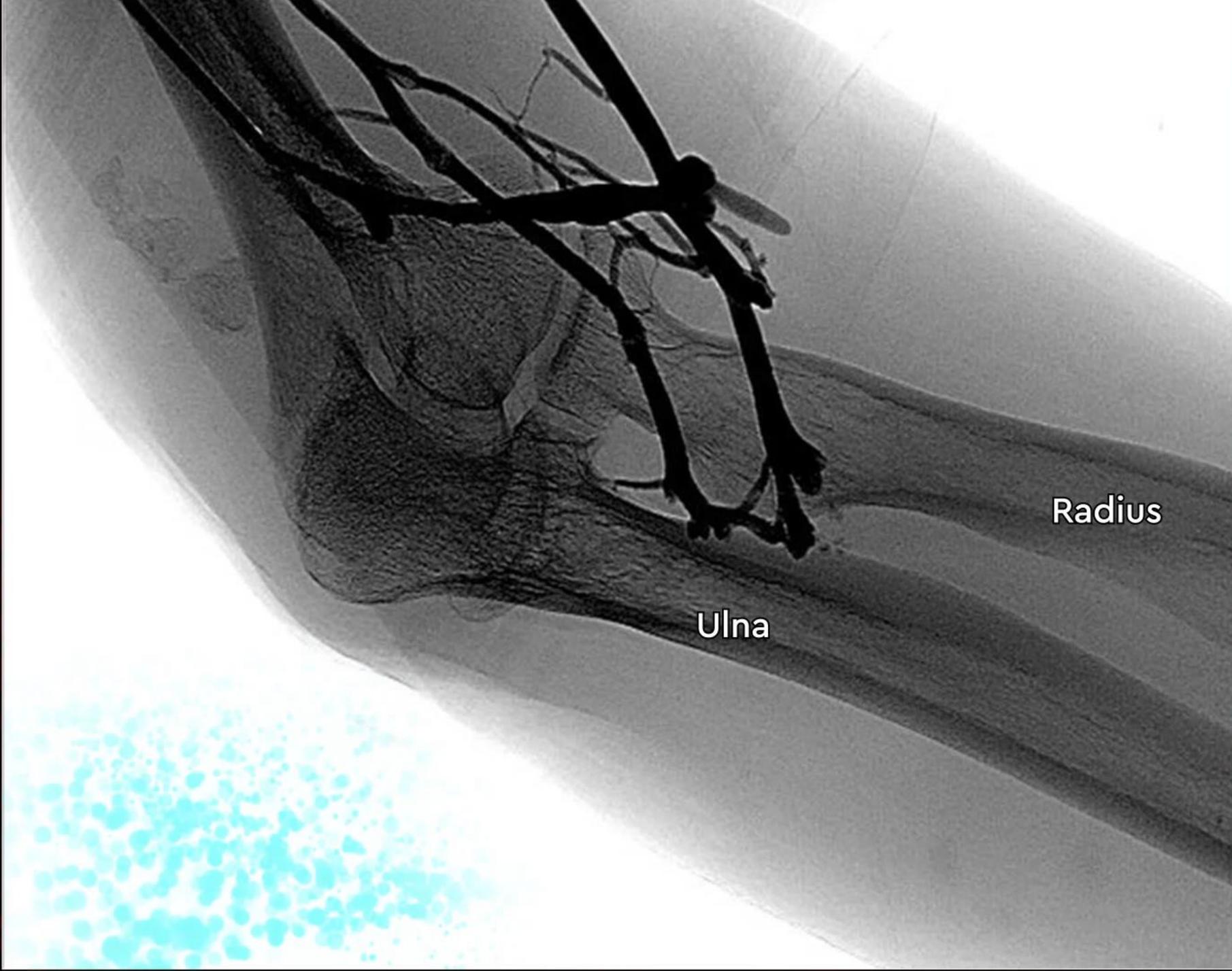






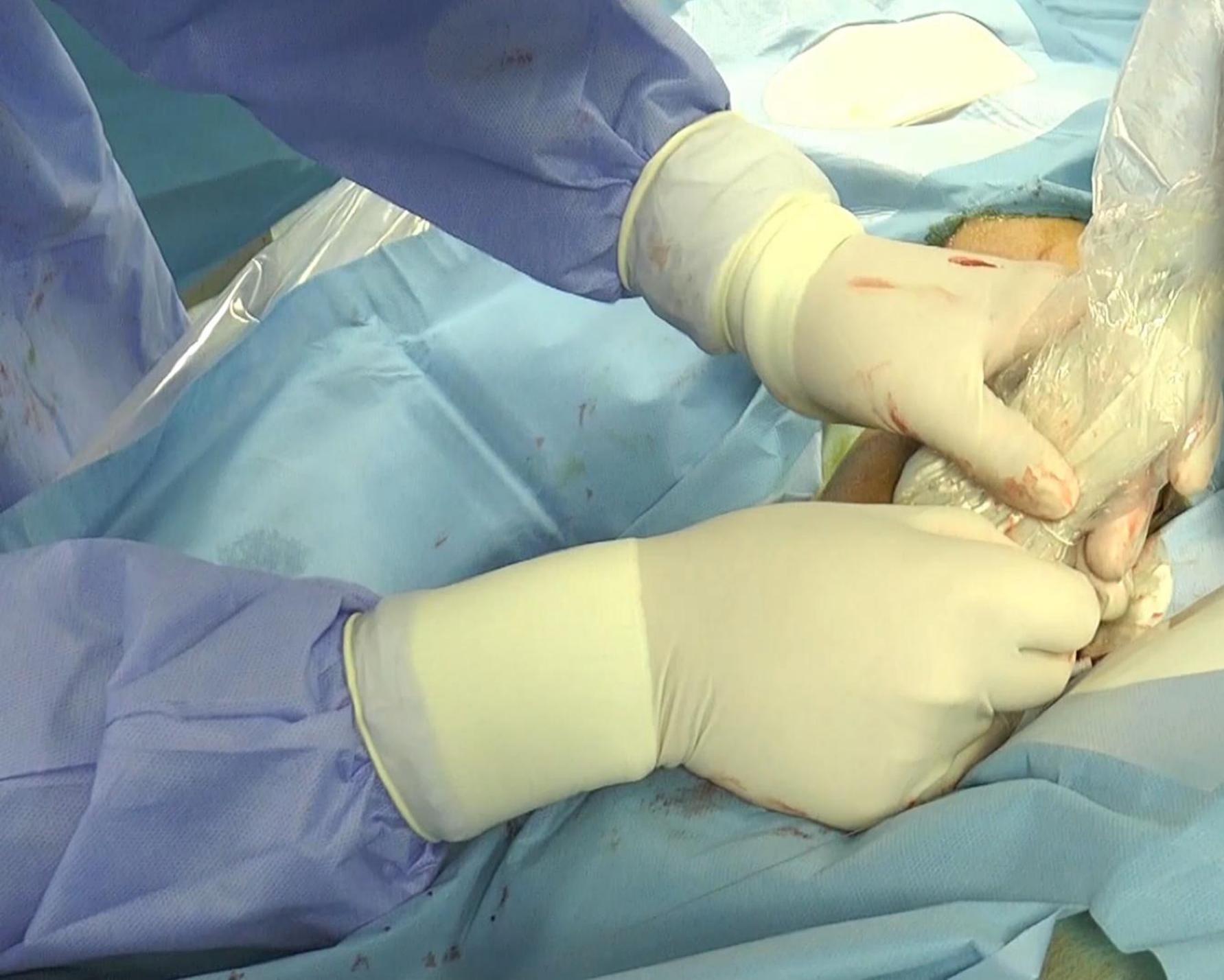






Radius

Ulna



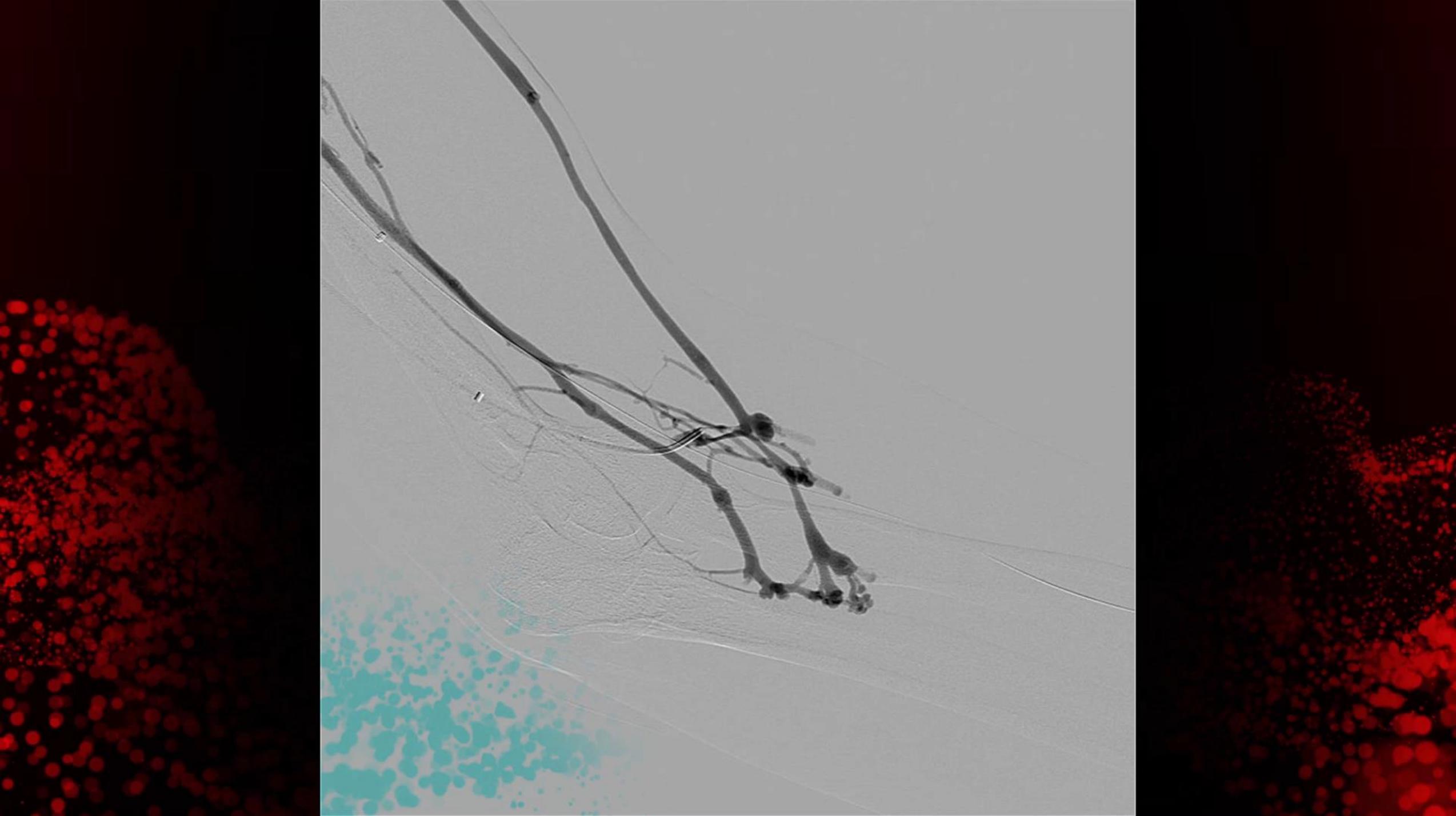


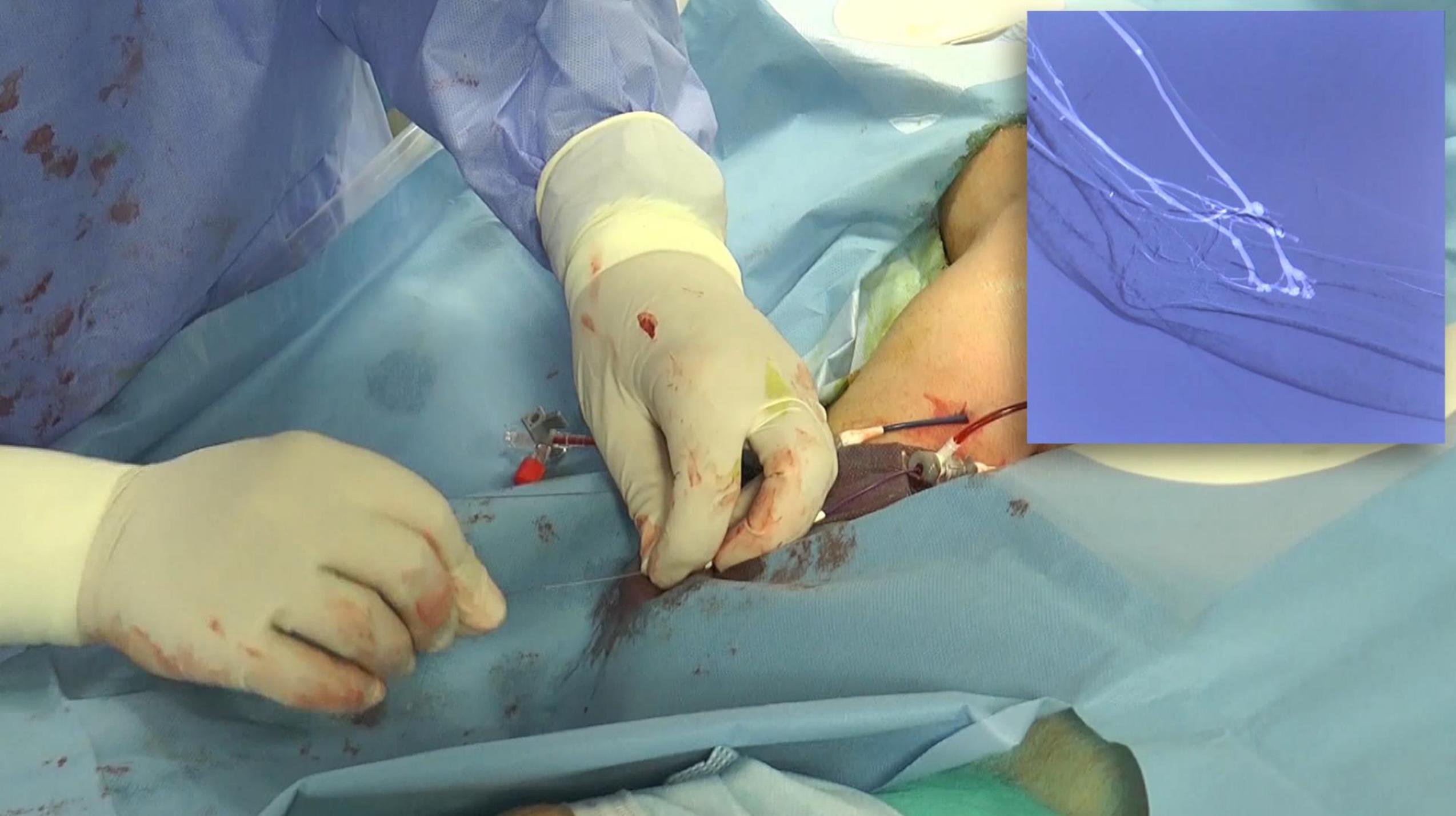


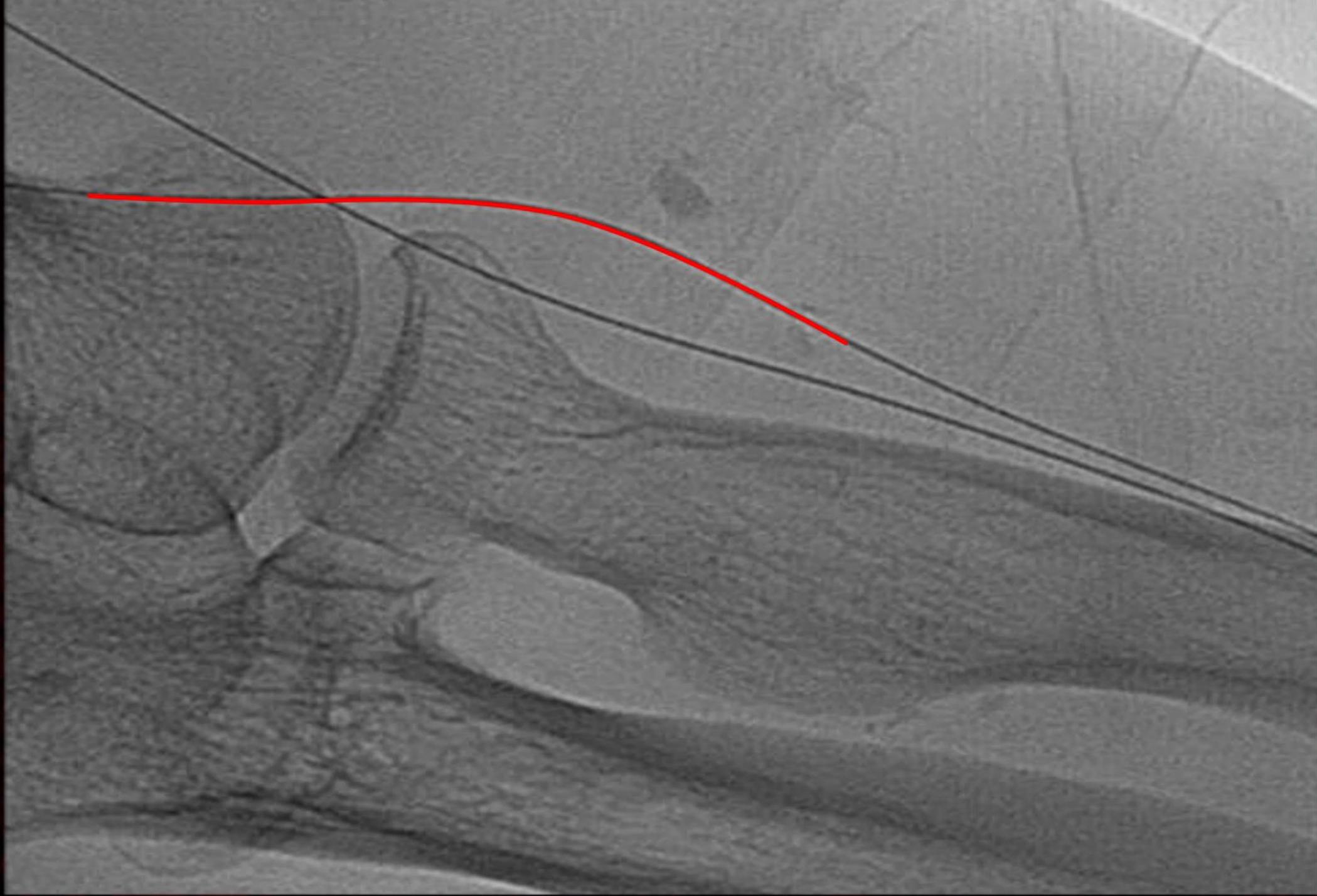


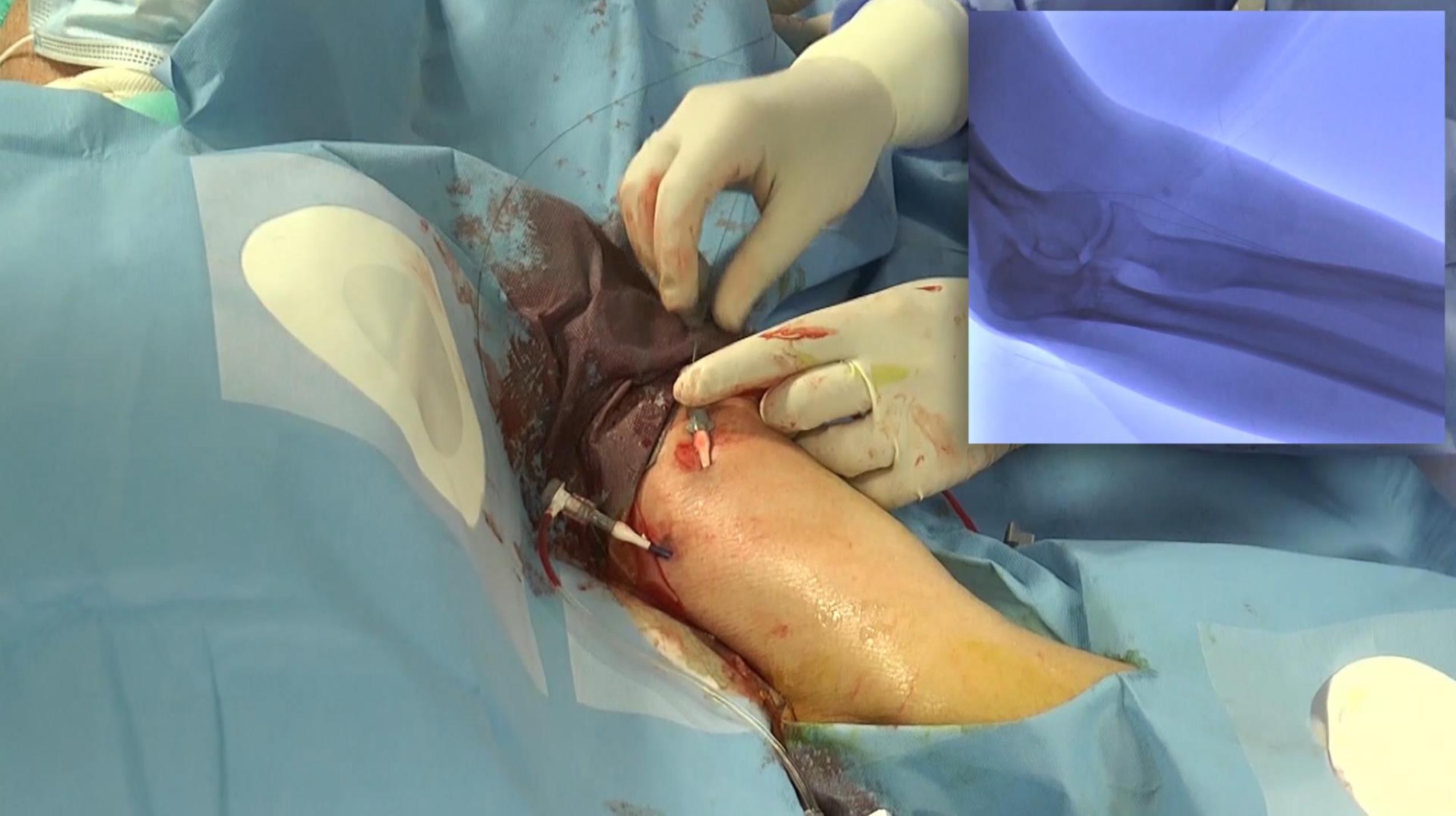


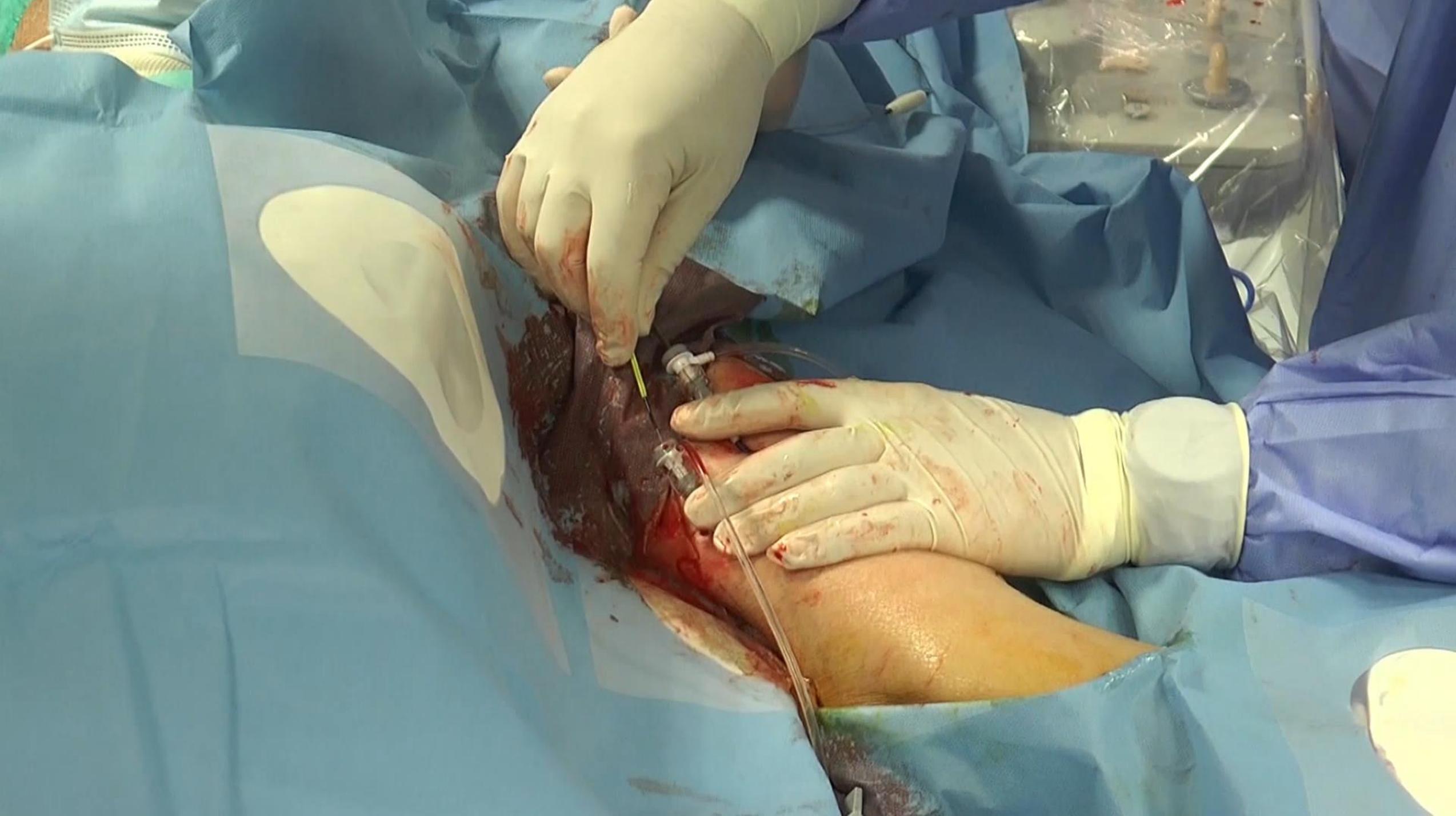


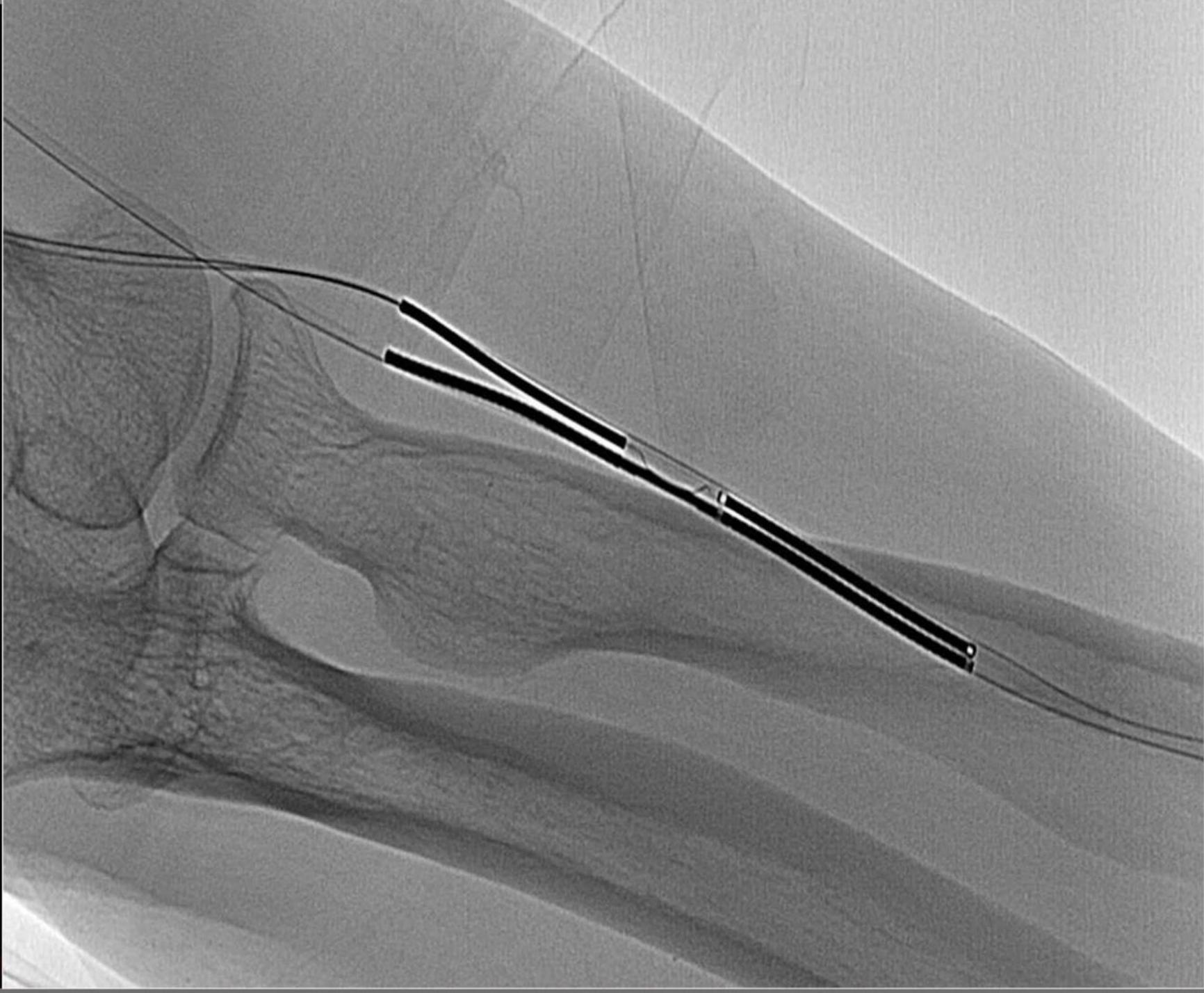




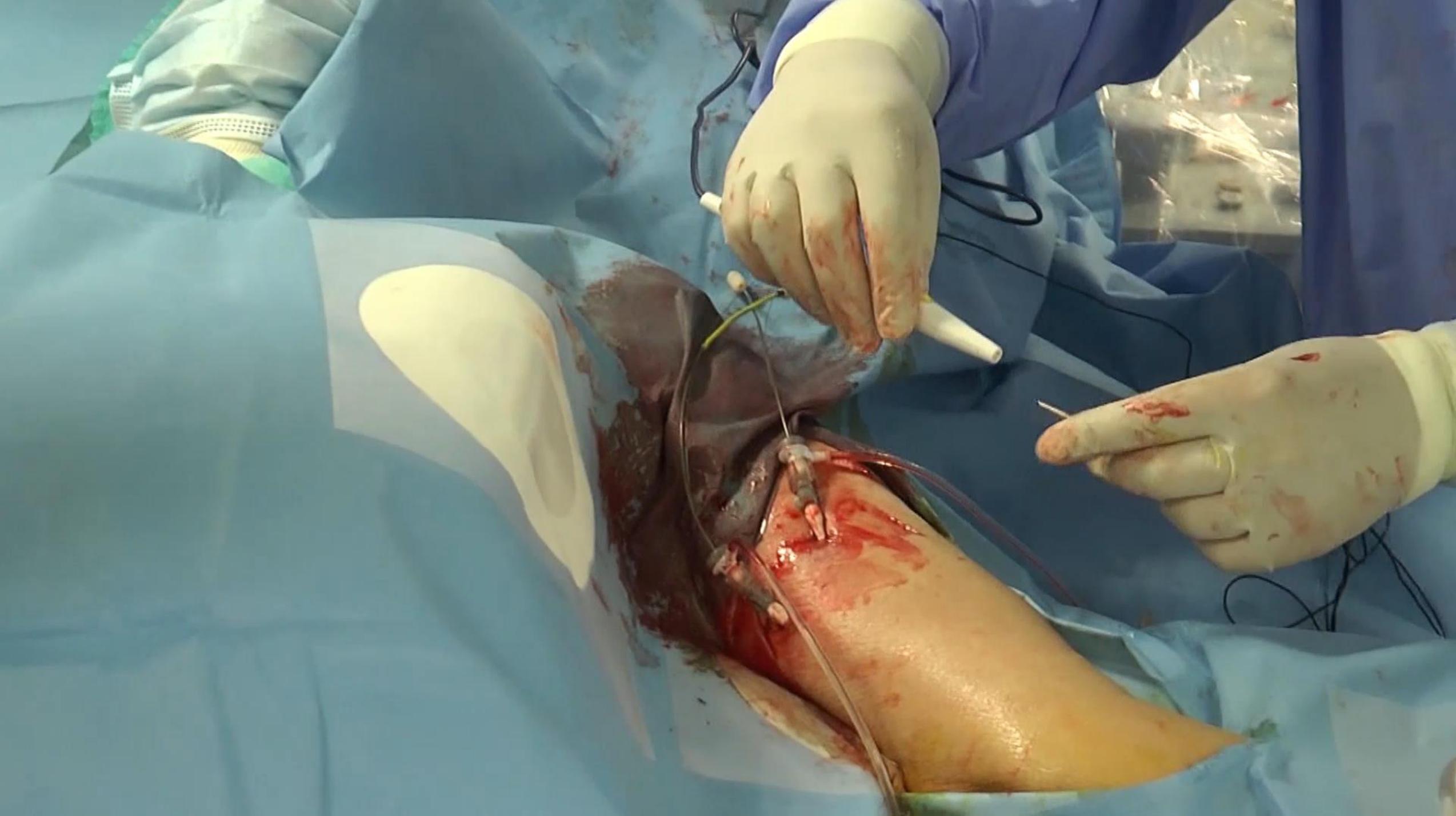


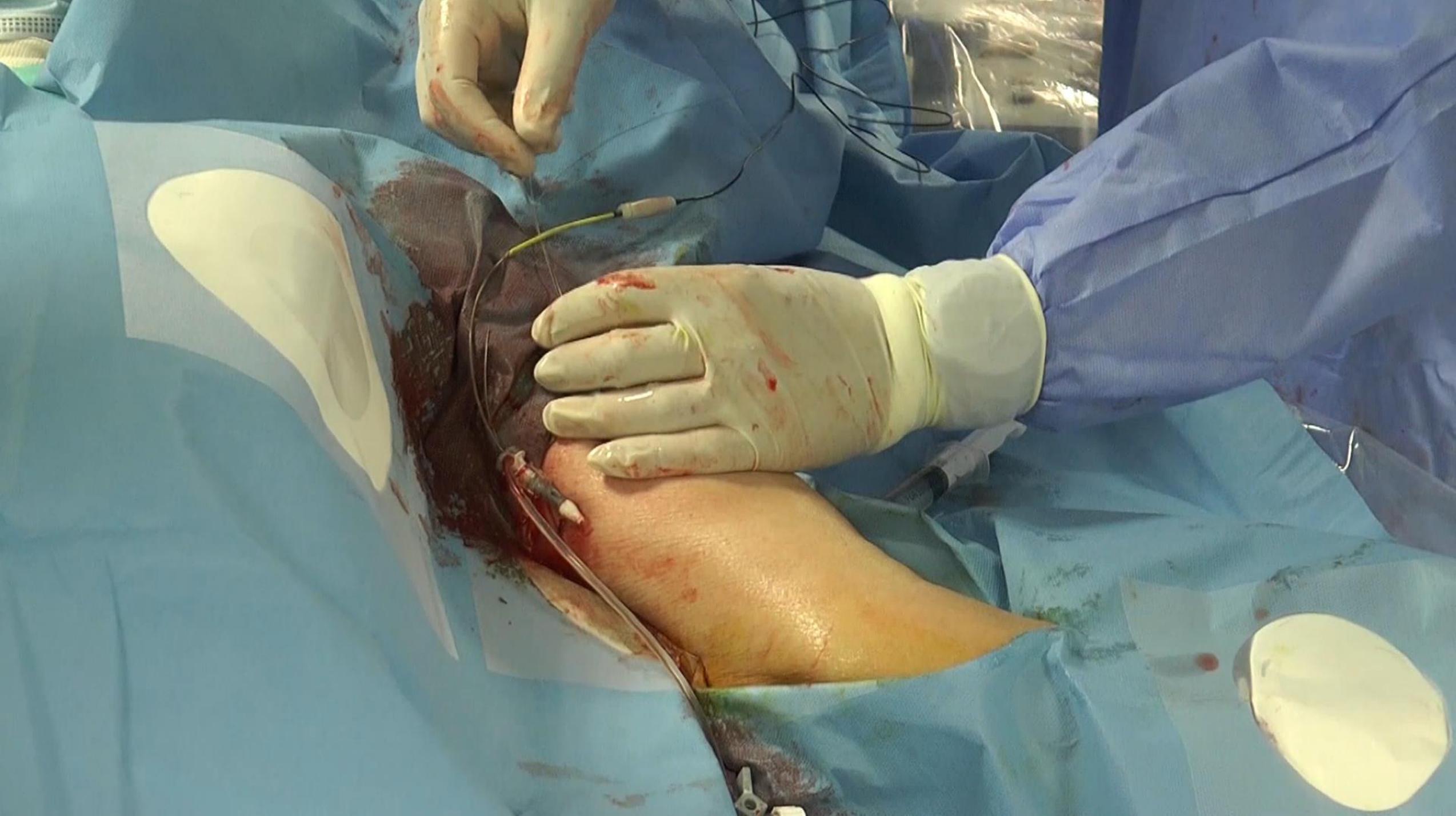


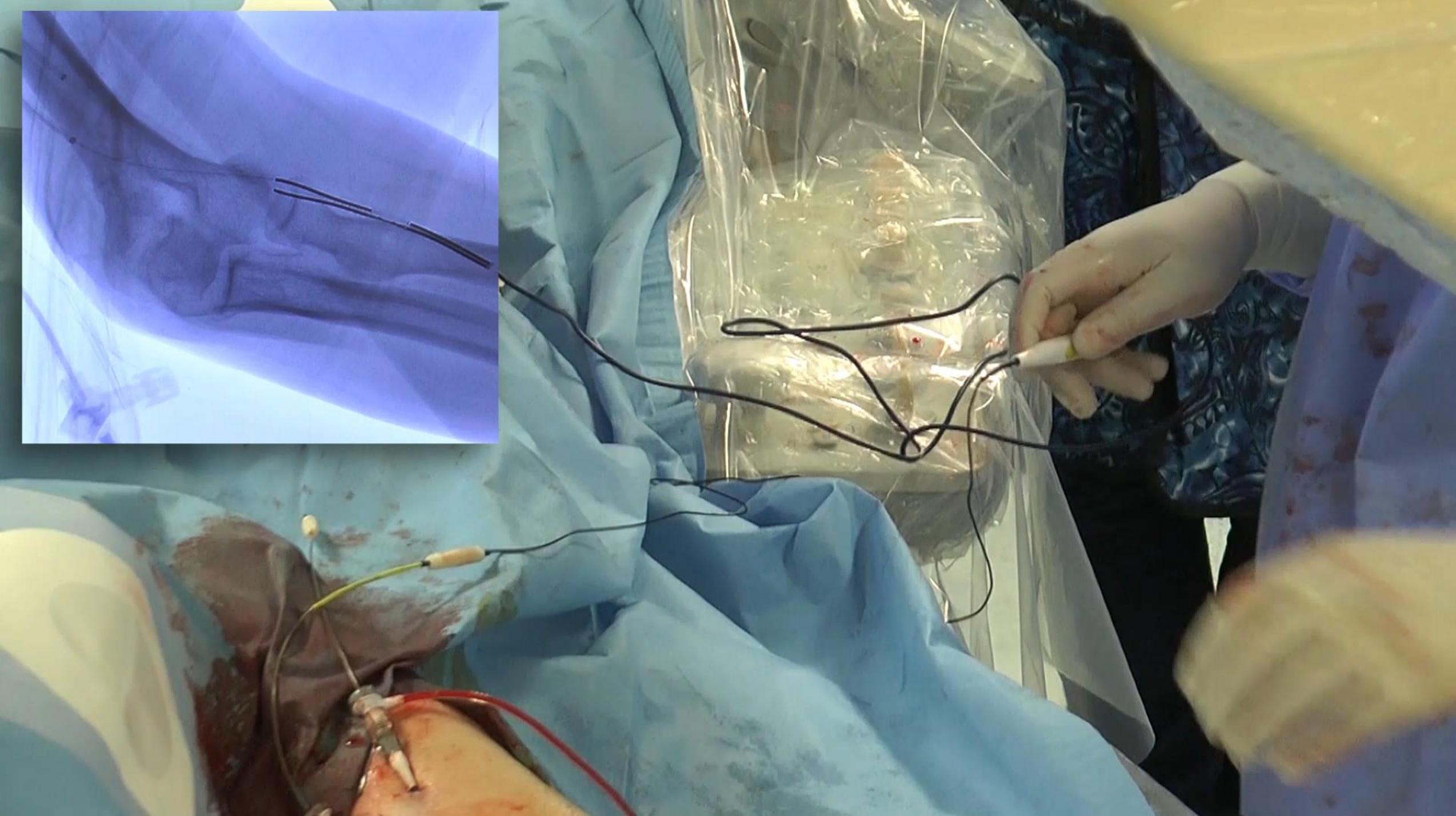


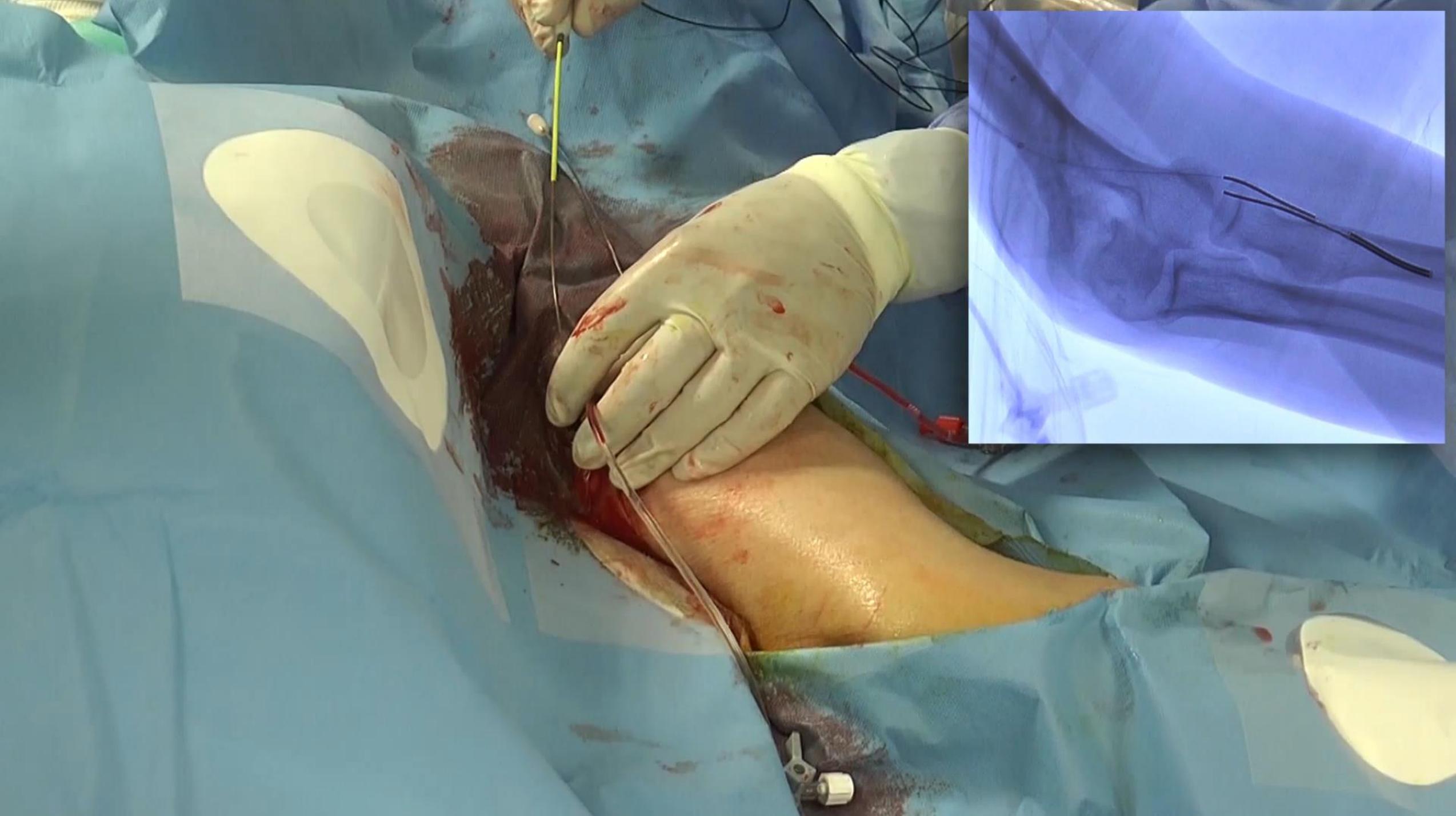






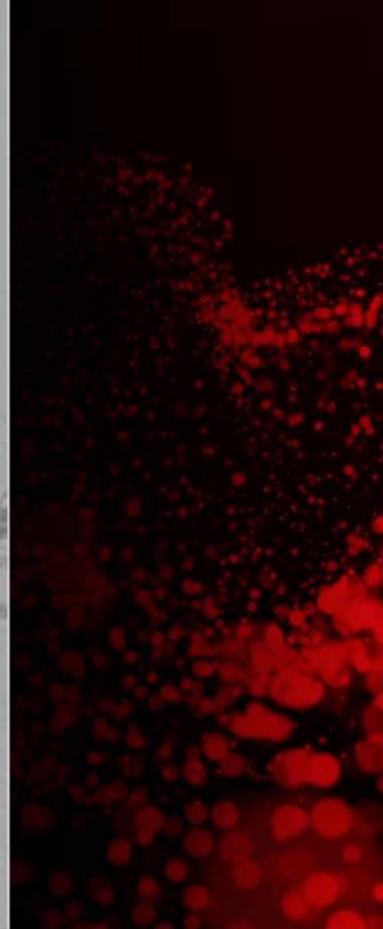
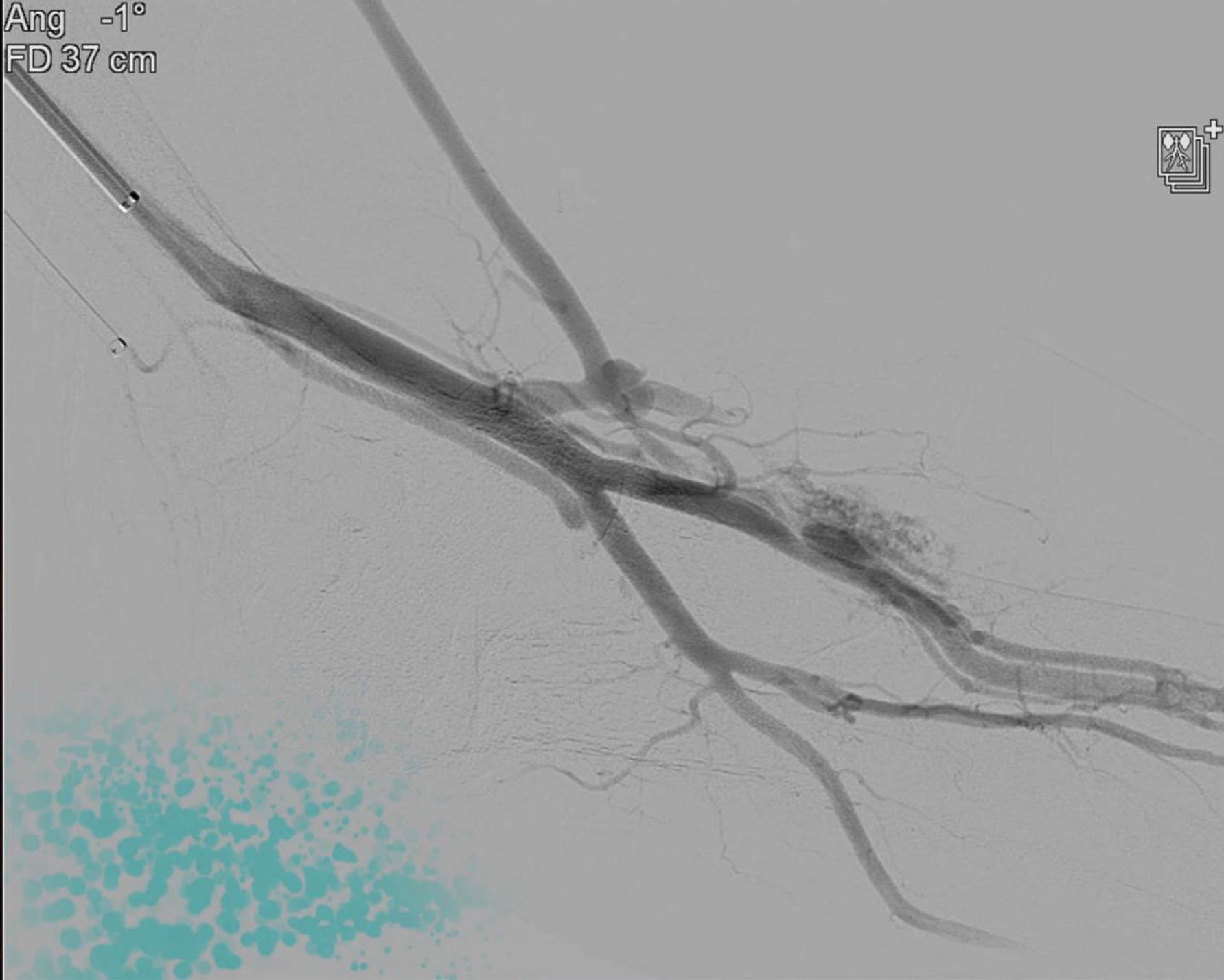
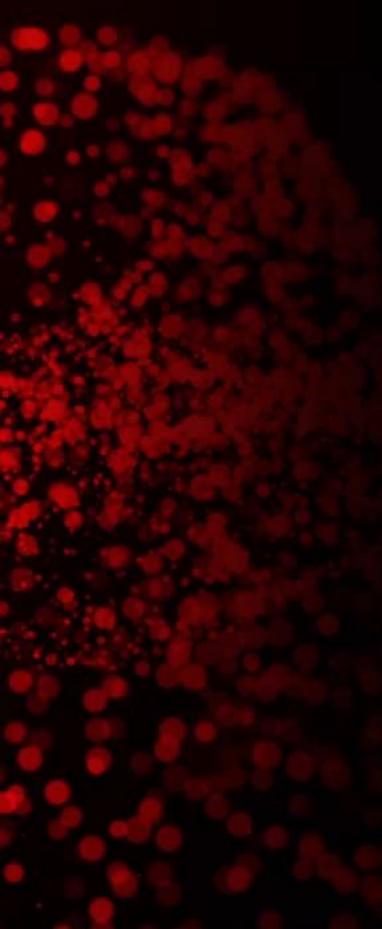






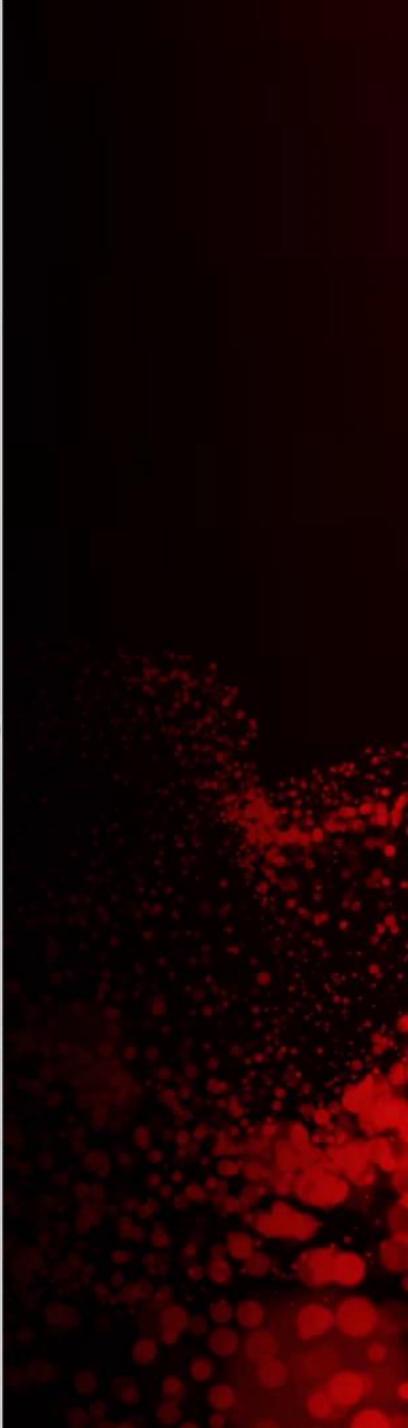
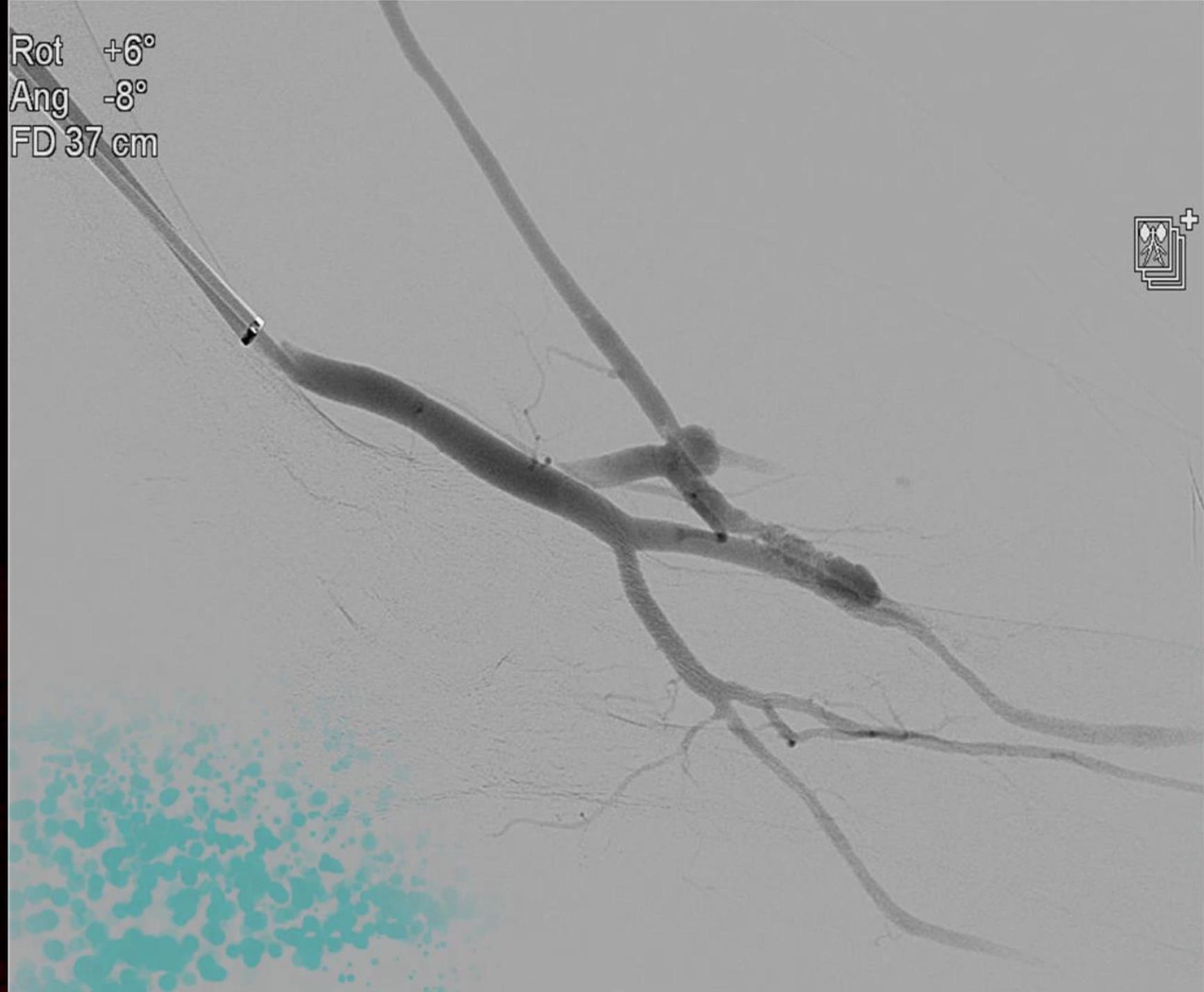


Ang -1°
FD 37 cm

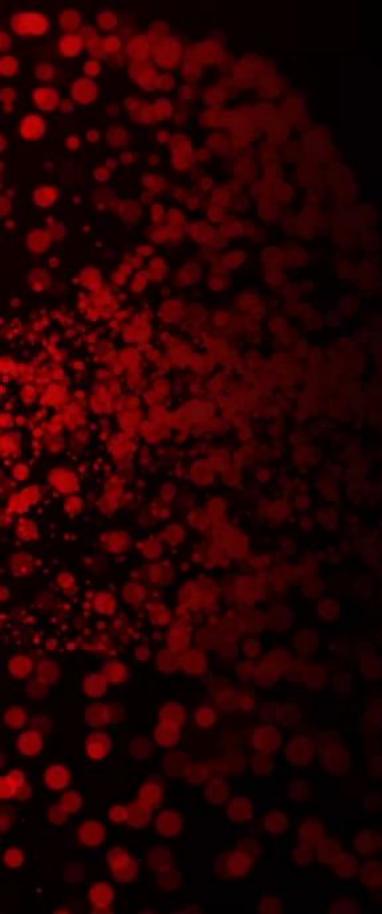




Rot +6°
Ang -8°
FD 37 cm



Rot +6°
Ang -8°
FD 37 cm



Case planning



50-year-old male



Pre-dialysis



Plan: To create Radial-Radial endoAVF



Access options:
Lat. Radial Vein (2.1mm) and Radial Artery (2.2mm)

Cannulation

Data Overview

BD Clinical program overview

		FLEX	NEAT	EASE	EUR/CA Post-Market	EASE-2
Device(s)	6F (Gen 1)	✓	✓		✓	
	4F (Gen 2)			✓	✓	✓
Fistula Location(s)	Ulnar-Ulnar	✓	✓	✓	✓	✓
	Radial-Radial			✓	✓	✓
Study Type	Prospective, single arm	✓	✓	✓	✓	✓
	Multiple operators	✓	✓	✓	✓	✓
	Multiple centers		✓		✓	
	Single center	✓		✓		✓
Study Details	Number of patients	33	60 (+20 roll-in)	32	100	24
	Location(s)	Paraguay	Canada, Australia, New Zealand	Paraguay	Germany, UK, Canada	Paraguay
	Status	<i>Rajan et al. Percutaneous Creation of an Arteriovenous Fistula for Hemodialysis Access (FLEX) JVIR 2015;26:484-490</i>	<i>Lok et al. Endovascular Proximal Forearm Arteriovenous Fistula for Hemodialysis Access: Results of the Prospective, Multicenter Novel Endovascular Access Trial Am J Kidney Disease 2017;70(4):486-497</i>	<i>Berland et al. Endovascular Creation of Arteriovenous Fistulae for Hemodialysis Access with a 4Fr Device: Clinical Experience from the EASE Study Annals of Vascular Surgery 2019;60:182-192</i>	Completed	Completed

WAVE GLOBAL

The WavelinQ™ Arterio-Venous Endovascular Fistula: A Global, Post-Market Investigation

Charmaine Lok, MD, MSc

Nicholas Inston, MD, PhD

Panagiotis Kitrou, MD, MSc, PhD

WAVE GLOBAL

Objective	A post-market study to observe the performance of the of the WavelinQ EndoAVF System when used for endovascular arteriovenous fistula (endoAVF) creation
Study Design	Prospective, single arm, multi-center, multi-operator NCT 04626427
Study Details	N=150 (estimated) Location(s): Global (excluding the US) Follow-up to 24 months Enrolling

www.clinicaltrials.gov

CONNECTAV
CLINICAL STUDY

Post-Market Surveillance Study of the BD[®] WavelinQ[™] EndoAVF System

Eric Peden, MD

Paul Kreienberg, MD

CONNECTAV

CLINICAL STUDY

Objective	Post-market surveillance of the WavelinQ™ EndoAVF System in patients requiring hemodialysis
Study Design	Prospective, single arm, multi-center, multi-operator NCT 04634916
Study Details	N= 280 (estimated)
	Location: United States
	Follow-up to 24 months
	Enrolling

www.clinicaltrials.gov

Summary

Announcing Two Prospective Multi-Center Studies

- Global patient population
- 430 subjects (est.)
- Key endpoints
 - # of interventions, functional cannulation, primary patency

WAVE GLOBAL

CONNECTAV
CLINICAL STUDY

WavelinQ™ EndoAVF System (WavelinQ™ System, WavelinQ™ or REF WQ4305) Components

Indications: The WavelinQ™ EndoAVF System is intended for the cutting and coagulation of blood vessel tissue in the peripheral vasculature for the creation of an arteriovenous fistula used for hemodialysis.

Contraindications: Known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation. Known allergy or reaction to any drugs/fluids used in this procedure. Known adverse effects to moderate sedation and/or anesthesia. Distance between target artery and vein > 1.5 mm. Target vessels < 2 mm in diameter.

Warnings: The WavelinQ™ EndoAVF System is only to be used with the approved commercially available devices specified in the IFU. Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system. The WavelinQ™ EndoAVF System catheters are single use devices. DO NOT re-sterilize or re-use either catheter. Potential hazards of reuse include infection, device mechanical failure, or electrical failure, potentially resulting in serious injury or death. Use caution when performing electrosurgery in the presence of pacemakers. Improper use could damage insulation that may result in injury to the patient or operating room personnel. Do not plug device into the electrosurgical pencil with ESU on. Keep active accessories away from patient when not in use. Do not permit cable to be parallel to and/or in close proximity to leads of other devices. Do not wrap cable around handles of metallic objects such as hemostats. Consult the ESU User's Guide on its proper operation prior to use. Do not use closure devices not indicated to close the artery used for access.

Cautions: Only physicians trained and experienced in endovascular techniques should use the device. Adhere to universal precautions when utilizing the device. Do not kink, pinch, cut, bend, twist, or pull excessively or with excessive force on any portion of the devices. Damage to the catheter body may cause the device to become inoperable. Avoid sharp bends. This may cause the device to become inoperable. Do not pinch or grasp the catheter with excessive force or with other instruments. This may cause the device to become inoperable. Do not bend the rigid portion of the catheter near the electrode or backstop. Do not touch or handle the active electrode. Electrode dislodgement may occur. Always use the hemostasis valve crosser to assist insertion of the venous catheter through the introducer sheath. Insertion into introducer sheath without hemostasis valve crosser may damage electrode. Do not attempt to remove the hemostasis valve crosser located on the venous device. Device damage or fracture may occur.

Precautions: Care should be taken to avoid the presence of fluid on the ESU. Care should be taken during handling of the arterial and venous catheters in patients with implantable cardiac defibrillators or cardiac pacemakers to keep the distal 3 inches of the catheters at least 2 inches from the implanted defibrillator or pacemaker. Care should be taken to avoid attempting fistula creation in a heavily calcified location of a vessel as fistula may not be adequately formed. The safety and performance of this device has not been established for pediatric patients. If the device does not perform properly during the creation of the endovascular fistula it is possible that a fistula will not be created or there may be some vessel injury. Keep magnetic ends of catheters away from other metallic objects which may become attracted and collide with devices.

Potential Adverse Events: The known potential risks related to the WavelinQ™ EndoAVF System and procedure, a standard AVF, and endovascular procedures may include, but are not limited to: aborted or longer procedure; additional procedures; bleeding, hematoma, or hemorrhage; bruising; burns; death; electrocution; embolism; failure to mature; fever; increased risk of congestive heart failure; infection; numbness, tingling, and/or coolness; occlusion/stenosis; problem due to sedation or anesthesia; pseudoaneurysm; aneurysm; sepsis; steal syndrome or ischemia; swelling, irritation, or pain; thrombosis; toxic or allergic reaction; venous hypertension (arm swelling); vessel, nerve, or AVF damage or rupture; wound problem.

Please consult product labels and instructions for use for all indications, contraindications, hazards, warnings and precautions.



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