Taryag
Medical

INSTRUCTIONS FOR USE

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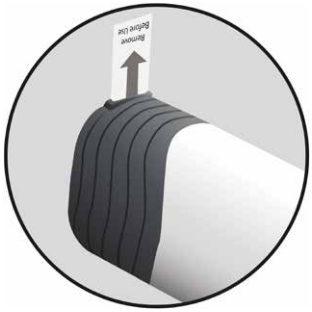
Instructions for Use

ByCross 6F 50cm	Ref. BC213-50
ByCross 6F 70cm	Ref. BC213-70
ByCross 6F 95cm	Ref. BC213-95
ByCross 6F 130cm	Ref. BC213-130

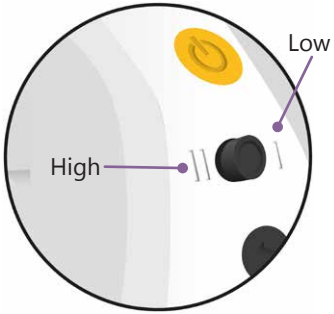
QUICK SETUP:

1 PREPARE:

- Visually inspect
- Pull and remove battery tab. Dispose of battery tab immediately after removal
- Slide to LOW – verify fixed GREEN LED, slide to HIGH – verify fixed GREEN LED
- Prime at front port



PULL TAB

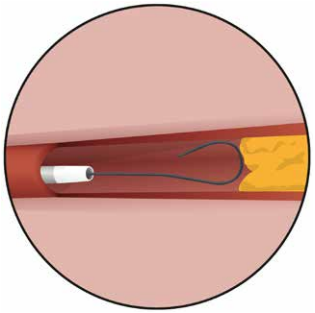


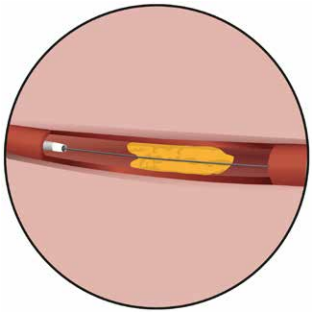
LOW / HIGH SWITCH

PRIME AT FRONT PORT

2 VERIFY:

- Place 0.035" guidewire distally from target, or, if blocked – facing target
- Place 6F or 7F sheath over the wire approx. 10cm from target
- VERIFY NO KINK OR SHARP BEND IN PUNCTURE SITE

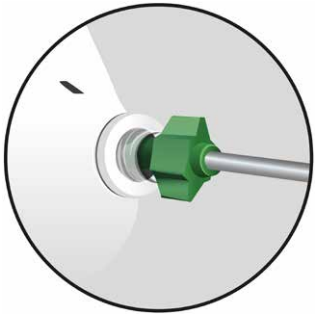


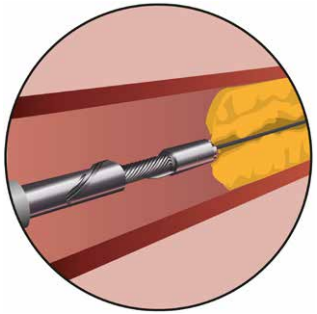


3

INSERT:

- Remove HAEMOSTATIC VALVE from Guiding Sheath
- Insert ByCross over the wire into the sheath – connect sheath LUER to ByCross
- Advance ByCross to target

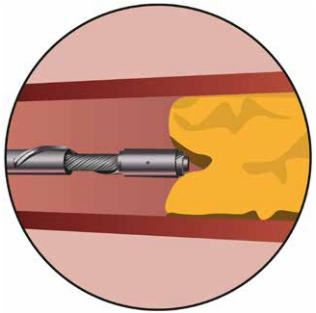




4

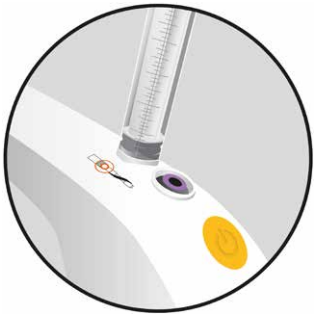
OPERATE:

- Slide to LOW, verify GREEN LED indicator, press button to activate
- MAX ADVANCMENT PACE:
  - SOFT material – 1cm in 5 seconds
  - HARD material – 1cm in 10 seconds
- HIGH – If required, stop, slide to HIGH, verify GREEN LED indicator and continue
- OPEN - If required, retract the device, OPEN WING and advance
- While running:
  - Advance 10-20mm, slightly retract, advance additional 10-20mm until crossed
  - DO NOT APPLY EXCESSIVE FORCE
- Without guidewire:
  - RETRACT WIRE 5-10cm from ByCross tip
  - Advance 10-20mm. STOP, advance the wire
  - If passage is possible, advance wire and continue over-the-wire
  - If wire passage is not possible RETRACT WIRE and repeat these steps until wire passage is possible
- Contrast medium:
  - While injecting contrast medium DO NOT APPLY EXESSIVE PRESSURE
  - If injecting through sheath, CLOSE STOPCOCK, REOPEN STOPCOCK right after



RETRACT 5-10CM

INJECT THROUGH TIP



INJECT THROUGH SHEATH

5

INDICATION:

- Fixed GREEN – READY
- Blinking GREEN – RUNNING
- FIXED RED – FAILURE – Turn OFF and ON, if reoccurs-replace device
- Blinking RED – Overload – Press REVERSE, slightly retract and continue

READY

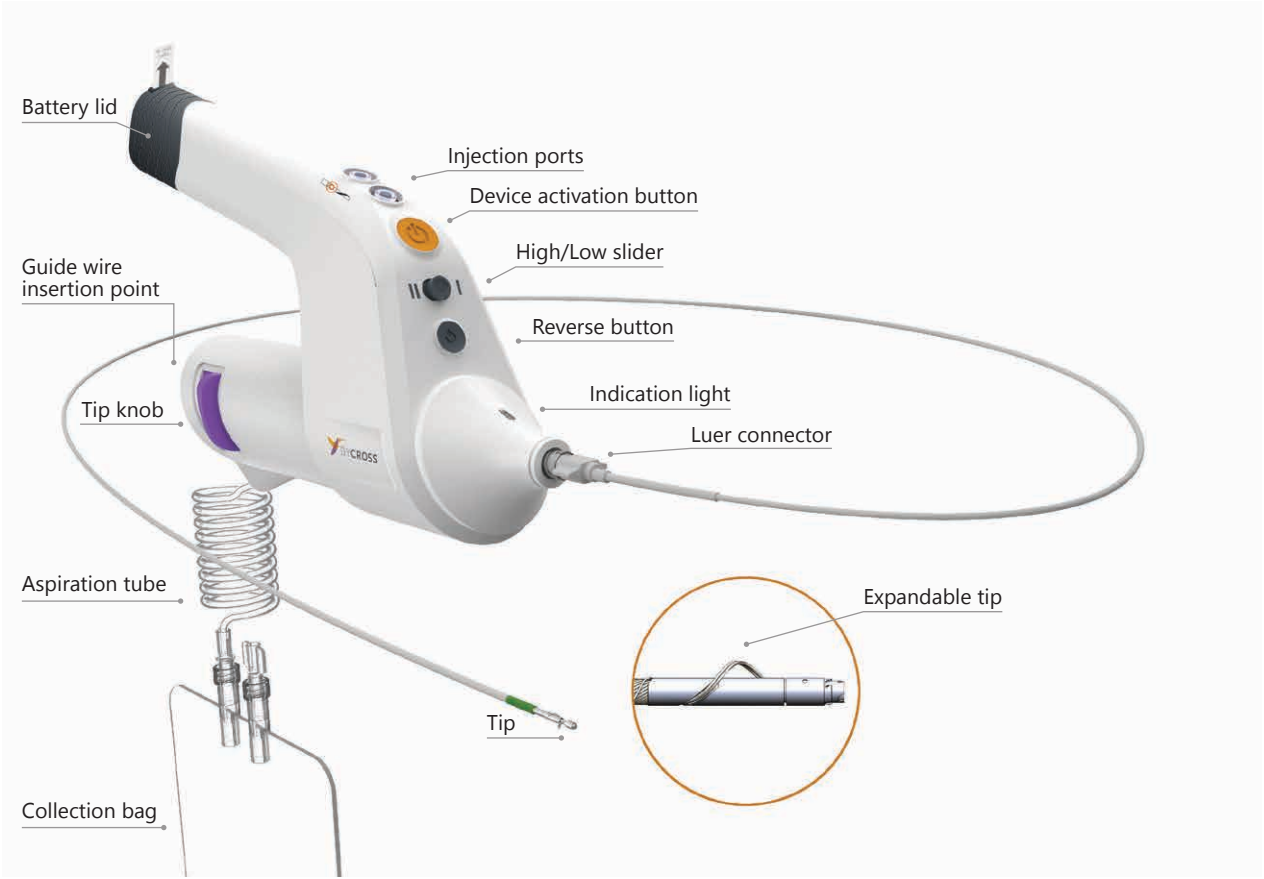
RUNNING

FAILURE

OVERLOAD

TABLE OF CONTENTS

1. BYCROSS PRODUCT DESCRIPTION



WARNING Read and understand these instructions before operating the device. Failure to do so may result in patient injury or death.

2. TECHNICAL DETAILS AND SPECIFICATIONS:

	Closed tip	Open tip
Designed to cross vessel diameters:	>3 mm	>5 mm
Tip external diameter:	1.9 mm	4.7 mm
Catheter length:	50 cm / 70cm / 95cm / 130 cm	
Catheter internal diameter:	0.95 mm	
Rotation HIGH:	4750 (+/-1000) rpm	
Rotation LOW/REVERSE:	2500 (+/- 600) rpm	
Maximum aspiration capacity:	70 ml/min @6F 170 ml/min @7F	

2.1 COMBINATION WITH OTHER DEVICES (NOT INCLUDED)

Guidewire	Standard 0.035" G.W. (of appropriate length)
Syringe	Any standard luer syringe
Guiding Sheath	Stainless Steel Reinforced 6F/7F (of appropriate length)

WARNING Insert and operate the ByCross device with the compatible devices as detailed above. Failure to do so, may result in inability to complete the procedure and/or patient injury.

TARYAG Medical Ltd. is not liable for any damage incurred as a result of the use of non-compatible devices. Product guarantee is annulled in these cases.

2.2 ORDER NUMBERS (REF.) AND NECESSARY MATERIALS NOT INCLUDED:

P/N	Name	Guiding Sheath Length
Ref. BC213-50	ByCross 6F 50cm	45cm
Ref. BC213-70	ByCross 6F 70cm	65cm
Ref. BC213-95	ByCross 6F 95cm	90cm
Ref. BC213-130	ByCross 6F 130cm	125cm

3. INDICATION FOR USE

The ByCross device is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid or renal vasculature.

4. STORAGE AND HANDLING

The products must be stored in their original packaging in a dry, dark place.

5. DESCRIPTION

The ByCross device is a single use, fully disposable, minimal invasive Atherectomy device (via catheter) which enables revascularization and restoring blood flow in occluded peripheral vessels as an alternative for bypass surgeries. The ByCross device has a coaxial flexible rotating shaft with an expandable tip, exchangeable guiding sheath, and simultaneous non-clogging aspiration system.

The expandable tip is an elastic arc that can bow and enlarge the tip diameter. As the shaft rotates, the tip breaks the atheroma or thrombus into small particles which are simultaneously aspirated into the catheter and removed to the attached collection bag. The ByCross device is powered by a disposable lithium battery pack and rotates at ~4750 (+/- 1000) rounds per minute. The ByCross device is introduced subcutaneous over a 0.035" guide wire.

NOTE

The ByCross device length must comply with the guide wire guiding catheter length.

WARNING

Limited to use by physicians familiar with endovascular techniques and the potential complications associated with treating intravascular atheroma and thrombosis.

CAUTION

Law restricts this device to be sold by, distributed by, or on the order of a physician.

CAUTION

Monitor the quantity of blood transported into the collecting bag at all times.

WARNING

Do not use in vessels of the central circulatory system, cardiopulmonary, coronary or cerebral circulations

WARNING

The ByCross device is intended to be used in a professional healthcare facility and only by specialized personnel who are trained in the relevant procedures of vascular intervention and have received training in application of the device.

WARNING

Insert and operate the ByCross device over the 0.035" guidewire of the appropriate length only. TARYAG Medical Ltd. is not liable for any damage incurred as a result of the use of non-compatible guidewires. Product guarantee is excluded in these cases.

6. TECHNICAL LIMITATIONS / CONTRAINDICATIONS

Use of the ByCross device is not permitted in the following cases:

- Patients not suitable for Thrombectomy
- Patients not suitable for Atherectomy
- Vessels of the cardiopulmonary, coronary or cerebral circulations
- Undersized vessel diameters
- Perforation of the vessel distally or proximally to the occlusion segment
- Subintimal position of the guiding catheter or the guidewire
- Use in stents or stent grafts if the guidewire has become threaded at any point in the wire mesh of stent or stent graft or the lining of the stent graft
- Target is at vessel segment which includes tortuous course with radius of curvature <= 40mm
- Access pathway includes tortuous course with radius of curvature <= 25mm
- In aneurysmatically altered vessel segments
- If the introducer sheath, the guide catheter, the guidewire or the ByCross sustains any damage, especially kinking
- In the fracture areas of broken stents
- Known or suspected allergy to any of the components of the system or to a medicinal product to be administered in connection with the planned procedure
- Persistent vasospasm
- During imaging by Magnetic Resonance Imaging (MRI)
- During use of a defibrillator on the patient
- Do not use if puncture site is at surgically exposed artery

The ByCross device should only be used if the benefit clearly outweighs the risk:

- In patients with haemodynamic instability or shock
- In patients with severe coagulatory disorders
- In situations where an embolism potentially triggered by the use of the ByCross device may have a very harmful effect on the patient
- In known or suspected infection, especially of the puncture site or the vessel segment being treated
- Known, unhealed pre-existing mechanical damage to the vessel wall, especially caused by surgical procedures or interventional complications
- If used in immature or not fully healed dialysis accesses or bypass grafts
- In broken stents

WARNING

To be used only outside fracture areas if it is impossible to achieve sufficient anticoagulation and platelet aggregation inhibition.

NOTE

Any serious incident*, except expected and documented side effect, that has occured in relation to the device shall be reported to Taryag Medical and the competent authority of the Member State in which the incident has occurred.

* Serious incident is any malfunction or deterioration in device performance related to the death or serious deterioration of patient or user health, or a serious public health threat.

7. POTENTIAL ADVERSE EFFECTS

Potential adverse effects include, but are not limited to:

- Embolisms, especially distal thromboembolisms
- Pulmonary embolisms of all degrees of severity
- Thrombosis, especially recurrent thrombosis
- Re-occlusion
- Vessel wall injury
- Vessel dissection / perforation / rupture
- Perforation as a result of a plaque being torn out of the vessel wall
- Arteriovenous fistula / pseudo-aneurysm
- Hematoma, bleeding, hemorrhage
- Implants such as stents / stent grafts / bypass grafts getting damaged, caught or dislodged
- Disruption of the ByCross device: debris remaining in the body
- Allergic reactions to the ByCross device materials
- Infections or necrosis at the puncture site
- Allergic reactions

8. WARNINGS AND PRECAUTIONS


WARNING

The ByCross device must not be used if a defibrillator and/or electrosurgery is being used on the patient: the products are electrically conductive. Remove the ByCross device from the patient before using a defibrillator and/or electrosurgery.


WARNING

The products are for single use and must not be re-sterilized.


WARNING

Reprocessing or re-sterilizing may severely impair the function of the product, which can cause injury, illness or death of the patient.


WARNING

Do not use the products if their sterile packaging barriers have been compromised or damaged.


WARNING

Do not use the products after the expiration date.


CAUTION

The ByCross device does not contain any parts that need to be maintained or serviced by the end-user. Do not repair or change the configuration of the device.

9. INSTRUCTIONS FOR USE

Preparation for use:


CAUTION

The ByCross should only be applied or used under adequate visual monitoring with suitable radiographic techniques.


WARNING

The ByCross device may only be used in the indicated diameters of target vessels. If a ByCross device is inserted into an undersized vessel diameter, the vessel can be ruptured by the rotating tip.

To determine the target vessel diameter, assess by suitable methods the narrowest nominal vessel diameter within the vessel segment to be treated.


WARNING

Do not use the ByCross device if the guiding sheath, the ByCross shaft or the guidewire are kinked.


WARNING

The guidewire must lie inside the vessel throughout its course from the introducing point to its flexible tip. If the position of the wire is subintimal or otherwise extraluminal – even for short segments – the ByCross device might be guided against the vessel wall when it is being advanced. This can result in vessel injuries such as dissection, perforation or rupture with potentially serious consequences for the patient.

1. Feed the 0.035" guidewire through the standard introducer sheath into the vessel.
2. Position the flexible tip of the guidewire as far distally as possible from the vessel occlusion being treated.
3. Flush the guiding sheath and dilator according to the standard procedure.
4. Introduce the guiding sheath over the guide wire.
5. Position the tapered tip of the dilator as far as distally possible towards the vessel occlusion being treated.
6. Remove the dilator out of the guiding sheath. The guide wire can be removed as well – according to the physician's needs.
7. Inject contrast media through the sheath and perform an angiogram to assure position of the sheath and condition of the vessel.

Taking out the ByCross device:

1. A non-sterile staff member shall:
   a. Verify that the length listed on the dust cover box label is the required length and the guiding sheath length used
   b. Take out the device packed in the pouch from the dust cover (carton) box
   c. Verify that the length listed on the pouch label is the required length, and compare with the length marked on the protective package to make sure the device length fits the label
   d. Visually inspect the pouch (sterility barrier) for tears/ rupture. If tears/ruptures are detected do not use the device
   e. Open the pouch from the top or the bottom side by holding the Tyvek layer and film layer above the short side seal and pulling them to open the pouch
   f. While holding the opened pouch at the Tyvek and film non sterile ends, and without touching the inner part of the pouch, protective package, or device; bring the opened pouch to a sterile staff member

WARNING

Any contact between a sterile staff member and the outer, non-sterile side of the pouch layers will contaminate the sterile staff member. Any contact between a non-sterile staff member and the inner side of the pouch layers, the protective package or device will contaminate the sterile device.

2. A sterile staff-member shall:
   a. Take out the protective package from the pouch held by the non-sterile staff-member
   b. Position the sterile protective package on a sterile surface and remove the ByCross device and the connected collection bag from its protective packaging.
3. Allow the rotating shaft to lay straight over the sterile surface.

Preparing the ByCross device for use:


WARNING

Before preparing the ByCross device always visually check the entire ByCross device carefully. Do not use the ByCross device if there is any damage or functional impairment.

1. Pull and remove battery tab. Dispose of battery tab immediately.


WARNING

After removal of battery tab, do not activate any of the device switches. Doing so may activate the motor and the rotating shaft may become coiled with other objects and may cause damage or become damaged.

2. The ByCross lumen must be filled with saline before the catheter is inserted into the introducer sheath and the blood vessel.
3. Using a sterile syringe with luer connector, fill the catheter by injecting saline through the front injection port at the head of the handle. Inject enough solution to fill the catheter lumen entirely, until the saline is washed out of the distal tip of the rotating shaft.
4. Remove the haemostatic valve from guiding sheath
5. Insert the deactivated ByCross device over the guidewire through the guiding sheath into the blood vessel. To prevent the rotating shaft from kinking outside of the introducer sheath, grasp the rotating shaft at a maximum distance of 3 cm from the guiding sheath and insert it in the direction of the longitudinal axis of the guiding sheath.
6. Advance the ByCross device over the guidewire through the guiding sheath to the front of the occlusion with the motor switched off. Repeat until the ByCross female luer connector can be connected to the guiding sheath male luer connector and the desired rotating shaft length is inserted and connected the luers. This is the starting position for the use of the ByCross device.
7. If the ByCross device was inserted over the guidewire, and guidewire passage of the occlusion cannot be facilitated, retrace the guide wire soft tip into the ByCross tip at least 5cm.


WARNING

When the starting position is reached, re-check the position of the guidewire tip and correct it if necessary. Activation of the ByCross device with the guide wire soft tip extending out of the rotating shaft tip may end in the separation of the guide wire tip from the guide wire or in the coiling of the guide wire around the rotating tip. This may result in vessel injuries such as dissection, perforation or rupture with potentially serious consequences to the patient.

WARNING

The ByCross device must always be guided to the starting position via a guiding sheath, which has been correctly positioned in the vessel. Use of the catheter without a guiding sheath may end in damage to the vessel wall as result of friction between the exposed rotating shaft and the vessel wall, or as a result of advancing the exposed ByCross tip along the vessel curves to the starting position.

WARNING

When using the ByCross device in stents or stent grafts, check very carefully that the guidewire is correctly positioned within the stent / stent graft lumen. Do not use the ByCross device if the guidewire has become threaded in the wire mesh of a stent, stent graft or the lining of the stent graft. Advancing the ByCross device over the threading point can seriously damage, destroy and/or dislodge the stent, stent graft or vessel.

WARNING

Do not operate the ByCross device in the fracture areas of broken stents or stent grafts, despite correct positioning of the guidewire. If a protruding stent strut penetrates the side of the rotating tip of the ByCross device, a strong torque might be applied to the stent or stent graft potentially causing the stent, stent graft or vessel severe damage or may destroy and/or dislodge it, or the ByCross rotating tip may get caught in the stent or stent graft in such a way that the ByCross device and the stent or stent graft have to be surgically removed.

WARNING

In native or synthetic bypass grafts or in native or synthetic dialysis accesses, only use the ByCross device if the anastomoses are healed and resilient and the graft is mature and healed. If a ByCross device is inserted before the anastomoses have become resilient and before a graft is mature and healed, the mechanical force exerted by the rotating tip on the occluding material and the vessel can cause injury to the anastomoses and/or the vessel.


WARNING

Under certain circumstances, the guidewire may become dislodged during catheter use. Monitor the correct position of the guidewire throughout the entire process of the catheter use. It is advisable to hold the section of the guidewire emerging at the proximal end of the ByCross device firmly so that manipulations of the ByCross device cannot alter the position of the guidewire.


WARNING

Do not start using the ByCross device before these preparatory measures have been completed.


NOTE

If injecting through the sheath, slightly retract tip and activate for 15 seconds to aspire clean blood, CLOSE STOPCOCK - INJECT - REOPEN STOPCOCK

Use of the ByCross device and treatment of the occlusion:

1. Use the front or rear ports to inject contrast media and perform an angiogram to assure position and condition of the ByCross tip in the vessel.
2. If the activation is performed using the device, hold the device in your hand.
3. After reaching the starting position for the ByCross device use and the correct position of the guidewire is achieved, move the slider switch from OFF to LOW position.


CAUTION

After moving the slider to LOW position, the ByCross device will be activated and will begin rotating once the activation button is pressed.

4. The light indication should be green to indicate that the ByCross device is ready for use. If the light indication is red, the ByCross device is not ready for use. Refer to the Troubleshooting section for further instructions.


WARNING

If used incorrectly, a catheter can traumatize and/or perforate the vessel being treated. Damage caused by vessel perforation is often serious and can result in the patient's death. Incorrect manipulation, such as kinking of the catheter, even outside the body, or over insertion should be avoided.


CAUTION

Assure that the device is held in a position that will prevent kinking of the rotating shaft.


CAUTION

Assure that the ByCross device can move in the insertion direction freely.

CAUTION

Assure that the collection bag is positioned in a way that will not disturb the procedure. The collection bag must hang vertically below the handle.

5. Press the activation button to run the motor. The shaft will start to rotate and the aspiration system will start to aspirate blood into the collection bag.
6. As the shaft rotates, the constant green light indication should start to blink.

CAUTION

If the indication light is a constant or blinking red, stop the procedure and refer to the troubleshooting section for instructions.

CAUTION

If the indication light is a constant green, stop the procedure and refer to the troubleshooting section for instructions.

7. Under fluoroscopy and with the motor running, advance the ByCross tip into the occlusion for no more than 10-20mm.
8. With the motor running continuously, guide the tip into the distally located open segment, then withdraw it to the starting point while keeping the motor running. After each advancement and associated opening of the corresponding vessel segment, withdraw the ByCross device a little way into the opened segment while the motor is still running so that the material removed can be processed and carried away.
9. In soft material the maximum advancement speed is one centimeter length per 5 seconds. If the material becomes harder, e.g. when reaching the underlying stenosis, the advancement speed must be reduced.
10. If the material becomes harder, e.g. when reaching the underlying stenosis, the rotating speed maybe changed from LOW to HIGH as necessary.

CAUTION

If the activated ByCross device is not kept at the right direction to the patient, or if the section of the ByCross device located outside the patient's body is not completely straight at all times, technical problems such as high friction of the rotating shaft or difficulties in the aspiration may occur.

WARNING

Initial crossing of the occlusion must be with a closed tip. Advancing the ByCross with an open tip may apply overload on the tip so that the tip may get severely damaged or destroyed and/or dislodged and may lead to perforation of the vessel wall.

CAUTION

If the activated ByCross experiences excessive load, the green indicator will turn to blinking red and the ByCross will stop the rotation immediately. Refer to the troubleshooting section for instructions.

11. Deactivate the motor by removing your finger from the activation button once the destination point has been reached.

12. Use the front or rear ports to inject contrast media and perform an angiogram to assure position of the ByCross tip and to determine the status of the treated vessel segment.
13. If the vessel condition and the occlusion length allow it, advance the guidewire soft tip to cross the occlusion.
14. If the guide wire cannot cross the occlusion and further activation of the ByCross device is required, retrace the guide wire soft tip into the ByCross tip, no less than 5cm.
15. Under fluoroscopy and with the motor running, advance the ByCross tip into the occlusion for no more than10-20mm.
16. Deactivate the motor by removing your finger from the activation button.
17. Use the front or rear ports to inject contrast media and perform an angiogram to assure position of the ByCross tip and to determine the status of the treated vessel segment.
18. If the vessel condition and the occlusion length allow it, advance the guidewire soft tip to cross the occlusion.
19. If the guide wire cannot cross the occlusion and future activation of the ByCross device is required, retrace the guide wire soft tip into the ByCross tip, no less than 5cm.
20. Repeat these steps until the guide wire tip is able to cross the occlusion.
21. After crossing the occlusion with the wire, position the guide wire tip as distally to the occlusion as possible.
22. Position the ByCross tip at the starting point. It is now safe to open the closed tip and to advance the ByCross tip over the wire along the occlusion.
23. To open the closed tip, pull the tip knob to the locking position.

CAUTION

When pulling/pushing the tip knob in order to expand or close the wing make sure the guide wire is not deformed as result of the knob movement.

24. Use the front or rear ports to inject contrast media and perform an angiogram to assure position of the ByCross tip and to determine the status of the treated vessel segment.
25. Use of the ByCross device can be repeated several times in order to achieve the optimal treatment outcome.

WARNING

Maneuvering the ByCross device through segments with heavily calcified plaques requires special care. These plaques may protrude into the vessel lumen. If the ByCross device is advanced too quickly, the tips of the plaque are aspirated only partially or not at all, and the plaque may cause distal embolization.

WARNING

Before removing the ByCross device from the patient with or without the guiding sheath, assure that the tip is closed. Removing the ByCross device with an open tip may damage the guiding sheath and may perforate the puncture site.

CAUTION

Blood and thrombus fragments in the sheath lumen might clot if the rotating shaft has stopped rotating. Therefore, if the ByCross device use is interrupted, the sheath and the ByCross lumen must be rinsed immediately in saline. To do this, remove the sheath from the rotating shaft and inject saline to fill the sheath. By injecting saline through the front injection port at the head of the device, rinse the ByCross lumen entirely, until the saline is washed out of the distal tip of the rotating shaft.

CAUTION

If the ByCross device is removed for any purpose out of the patient's body, it must be rinsed as described above. Reinsert the rinsed catheter into the blood vessel to restart the procedure.

Removal and disposal:

WARNING

Further treatment of used products and their disposal need to be handled in accordance with international medical codes of practice, taking into consideration relevant local laws.

26. To complete the treatment with the ByCross device, move the slider switch to OFF position and close the tip. Carefully remove the ByCross device via the guiding sheath.

27. Remove the battery lid to separate the ByCross device battery by pushing the lid sideways and pulling it away.

CAUTION

To keep the batteries as non-biohazard, do not touch the batteries with contaminated gloves / hands. Remove the exposed batteries with clean gloves / hands only.

28. Hold the battery pack and pull the pack out of the handle.
29. Dispose of the batteries in designated container for Lithium battery waste.
30. Dispose of the ByCross device in designated container for bio-hazard medical equipment waste.

10. TROUBLESHOOTING

Error / Problem / Trouble	Possible cause	First corrective action	Second corrective action
Light indication turns to constant red	Activation button pressed immediately after slider moved to LOW/HIGH	Release activation button, slide LOW/HIGH slider to OFF position, slide the slider back to LOW/HIGH and reactivate	Replace with a new ByCross device
	Susceptibility of the device to electrostatic discharge		
	Low battery		
	Major failure of electrical components or failure in the self-internal check		
Light indication turns to blinking red	Overload on the motor	Push the reverse button to rotate the shaft clockwise for 0.5 sec.	Make sure there is no kink of the shaft or the guide wire, remove the ByCross device and repeat procedure
No rotation (with green light indication)	Low battery or electrical contact failure	Replace with a new ByCross device	
No aspiration / poor aspiration	The collection bag tube is kinked	Assure that there is no kink along the collection tube	Remove the ByCross device and flush the guiding sheath
	The removed material along the shaft caused blockage	Allow the rotating shaft to rotate and to aspirate the material without advancing the ByCross device	

Error / Problem / Trouble	Possible cause	Corrective action	Remark
Difficulty inserting the guide wire tip into the distal end of the rotating shaft	The guide wire diameter >0.035" / damaged	Replace guide wire	Wet the guide with saline
	The ByCross tip is blocked with clot / damaged	Flush the rotating shaft with saline	Replace with a new ByCross device
Difficulty inserting the guide wire soft tip into the tip knob	The soft tip cannot penetrate the sealing	Use the original J strainer of the guide wire	If necessary - replace with a new ByCross device
The soft tip of the guide wire is coiled around the tip inside the vessel	The tip rotated while the guide wire tip was not inside the lumen	Carefully remove the ByCross device and the guide wire together as one part. Replace with a new ByCross device	
The rotating tip is lodged in the occlusion with no possibility to remove the ByCross device	The tip is caught inside hard occlusion material	Inject contrast material to assure position of the tip. Push the reverse button to rotate the shaft clockwise for 1.0 sec.	Disconnect the guiding sheath of the handle. Advance the guiding sheath into the occlusion and release the tip
The collection bag contains air which aspirated inside	Air is aspirated through the guiding sheath luer connection to the device	Assure that the luers are well connected	
Injection of contrast material is not possible	The guide wire lumen is blocked with the removed material	Insert guide wire until the soft tip extends out of the ByCross tip	Remove the guide wire out of the ByCross device
Crossing the occlusion not possible due to lack of power	Hard atheroma created high load on the rotating shaft	Assure that the tip is closed	Switch to HIGH power and advance the ByCross device slowly into the occlusion
The Guidewire can no longer be removed out of the rotating shaft	Damage of the guide wire or the rotating shaft	Disconnect the guiding sheath from the device and remove the ByCross device from the body	

Error / Problem / Trouble	Possible cause	Corrective action	Remark
Difficulty to introduce the ByCross device through the guiding sheath	The ByCross device outer diameter does not fit the guiding sheath inner diameter	Assure that the correct guiding sheath is being used, and that there are no kinks along the sheath	Assure that the tip is closed
Poor aspiration power	Hard material aspirated and damaged the pump valves	Remove the device from the body. Detach the collection bag from the device. Attach a 5ml luer syringe to the device outlet. Inject 5ml saline into the device.	
No aspiration			

11. SPECIFICATIONS

Characteristic	Specification
Models	ByCross 50cm P/N BC213-50
	ByCross 70cm P/N BC213-70
	ByCross 95cm P/N BC213-95
	ByCross 130cm P/N BC213-130
Guidewire Exchange	Introduced over-the-wire. During operation, if passage of occlusion with the guidewire cannot be facilitated - wire can be retracted 50mm from the tip
Compatible guidewire size (inch)	0.035"
Compatible guiding sheath	Stainless Steel Reinforced 6F/7F
Tip mechanism	Expandable tip. An elastic arc that can bow when knob on handle is pulled, and enlarge the tip crossing profile diameter
Tip diameter	1.9mm @ closed tip
	4.7mm @ expanded tip
Target vessel size	≥3mm @ closed tip
	≥5mm @ expanded tip
Nominal rotation speed	HIGH mode – 4750 R.P.M
	LOW mode – 2500 R.P.M
	Reverse mode – 2500 R.P.M
Activation modes	OFF/HIGH/LOW – selectable by slide switch Forward (HIGH or LOW) upon pressing FORWARD tactile switch Reverse upon pressing REVERSE tactile switch. Activated for duration of 0.5 seconds
Debris collection	Vacuum aspiration for continuance removal of excised debris
Aspiration flow	@6F 30-70 ml/min, @7F 110-170 ml/min
Power source	ByCross Device - Internal 12V battery pack
Use	Single use
Sterilization	Ethylene Oxide
Rotating shaft materials	Stainless Steel SS304, PFA, Nitinol
Package	Die-cut card pack sealed Tyvek pouch, packed in outer carton box
Package content	Package includes ByCross device and Collection bag. A copy of the IFU is packed inside the outer box

12. SYMBOLS AND DESCRIPTIONS

Symbol	Description
	Do not use if the package is damaged
	Do not re-use
	Do not resterilize
	Keep away from sunlight
	Keep dry
STERILE EO	Sterilized using Ethylene Oxide
LOT	Lot number
REF	Catalog number
	Use by date
	Follow instructions for use
	Manufacturer
	Type CF Applied Part

Symbol	Description
MD	Medical Device
IP33	IP Rating
	Single sterie barrier system with protective packing inside
EC REP	European Authorized Representative
CE 0483	Identification of notified body

Electrical specifications:

Parameter	Specification
Power source	Internal
Type and degree of protection against electrical shock	Applied part – Type CF
Degree of protection against ingress of water or particles	IP33 – Protected from particles > 2.5mm (0.098 in), protected from liquid falling as a spray at any angle up to 60° from vertical

13. ELECTROMAGNETIC COMPATIBILITY

- ByCross complies with EN 60601-1-2: 2015 + A1: 2021 Edition 4.1 (IEC 60601-1-2: 2014 + A1: 2020 Edition 4.1), Sections 7, 8, professional; healthcare facility environment, group 1, class A
- Since the intensity of electromagnetic energy is greatest near the source of a transmitting antenna, portable and mobile RF communications equipment can affect medical electrical equipment.
- In case of unexplained interference, consider the locations of nearby transmitters or devices which can emit a high level of electromagnetic energy (above the levels of EN/IEC 60601-1-2) and can produce interference.
- The use of accessories made or partly made from metal other than those specified in the ByCross IFU and include guidewire and SS reinforced 6F and 7F sheath, may result in increased emissions by the device or decreased immunity of the device

1. Guidance and declaration – electromagnetic emissions

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPER 11	Group 1 Class A	The ByCross device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The ByCross device is suitable for use in healthcare establishments. It is not suited for used in domestic establishments.

2. Guidance and declaration – electromagnetic immunity

Immunity test	IEC 60601 level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-4	Air discharge: 2, 4, 8, 15kV Contact discharge: 8kV	Air discharge: 2, 4, 8, 15kV Contact discharge: 8kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

3. Guidance and declaration - Electromagnetic Immunity for NON life-supporting Medical Equipment and Medical Systems

Immunity test	IEC 60601 level	Compliance level	Electromagnetic environment - guidance
ByCross device is intended for use in the electromagnetic environment specified below. The user of the ByCross device should assure that it is used in such an environment.			
Portable and mobile RF communications equipment should be used no closer to any part of the ByCross device than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000-4-6	3 Vrms prior to modulation and 6 Vrms in ISM bands	3 Vrms and 6 Vrms	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3Vrms/m 80-2700 MHz	[E1] 3 V/m	Recommended separation distance: $d = 1.2\sqrt{P}$, 80 – 800 MHz range $d = 2.3\sqrt{P}$, 800 – 2700 MHz range

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE 3: P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

NOTE 4: Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.

NOTE 5: Interference may occur in the vicinity of equipment marked with the following symbol:

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ByCross device is used exceeds the applicable RF compliance level above, the ByCross device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ByCross device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Immunity test	IEC 60601 level	Compliance level	Electromagnetic environment - guidance
Radiated RF – proximity fields from wireless equipment IEC 61000-4-3	27Vrms/m 385 MHz pulse modulation 18 Hz	27 V/m	Service: TERA 400
	28Vrms/m 450 MHz pulse modulation FM, ±5kHz deviation, 1kHz sine	28 V/m	Service: GMRS 460, FRS 460
	28Vrms/m 810, 870, 930 MHz pulse modulation 18 Hz	28 V/m	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5
	28Vrms/m 1720, 1845, 1970, 2450 MHz pulse modulation 217 Hz	28 V/m	Service: GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25;, UMTS
	28Vrms/m 1720, 1845, 1970, 2450 MHz pulse modulation 217 Hz	28Vrms/m 1720, 1845, 1970, 2450 MHz pulse modulation 217 Hz	28Vrms/m 1720, 1845, 1970, 2450 MHz pulse modulation 217 Hz
	28Vrms/m 710, 745, 780, 5240, 5500, 5785 MHz pulse modulation 217 Hz	28 V/m	LTE Band 13, 17, WLAN 802.11 a/n

4. Recommended separation distance between portable and mobile RF equipment and the ByCross device (NON life-supporting Medical Equipment)

Rated maximum output power of transmitter, W	Separation distance according to frequency of transmitter, m		
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $=d = 2.3\sqrt{P}$
The ByCross device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ByCross device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ByCross device as recommended below, according to the maximum output power of the communications equipment.			
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.4
100	12	12	23
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			

Cyber security

- The ByCross device does not interface with any other device. It has no communication or electrical ports and connectors
- The ByCross device has no wireless communication capability of any kind
- The ByCross device contains firmware embedded in its motion controller. It is not accessible to the user
- Inherent by its sterile and single use nature, any attempt to open the device is prohibited by any person, and disqualify the device from clinical use

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