

INSTRUCTIONS FOR USE

Accura Finebent

Peripheral Vascular Self-Expanding Stent System

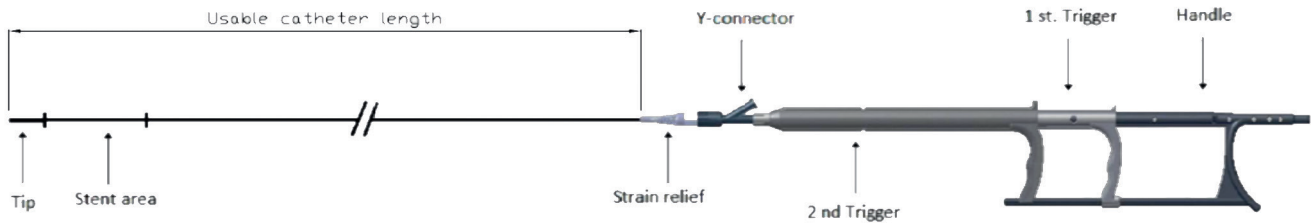


Figure 1 Stent system

STERILE: Sterilized with ethylene oxide. Do not use if the sterile package is open or damaged.

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions; otherwise, complications may occur.

Use the product before expiration of the „Best-Before-Date” mentioned on the packing.

Description

Please use the product illustrations above to guide you through the device description.

- The Finebent is designed to deliver a self-expanding stent to the peripheral vasculature via a sheathed delivery device. The Finebent is comprised of the following:
- An implantable self-expanding nickel-titanium alloy (nitinol) stent, as shown in Figure 2. The stent is flexible, a fine tubular mesh prosthesis, with a helical design, which achieves its unconstrained diameter upon deployment into the target vessel. Upon deployment, the stent imparts an outward radial force on the luminal surface of the vessel to establish patency.

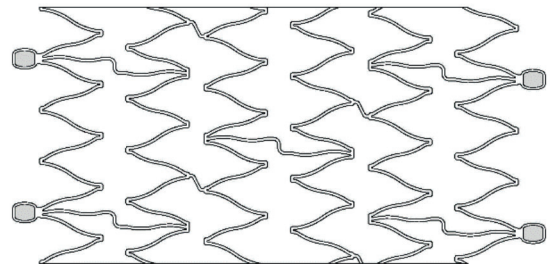


Figure 2 Nitinol Stent

- A stent system, as shown in Figure 1, comprised of an inner tubing assembly that contains the guide wire lumen, a stent delivery sheath and a system stability sheath, which are linked together by means of a handle. The guidewire lumen terminates distally in an atraumatic delivery device catheter tip and originates proximally in a luer hub designed to accept a compatible guide wire.
- The self-expanding stent is constrained in the space between the guide wire lumen and stent delivery sheath. Unintended stent movement during sheath retraction is restricted by the delivery device. The stent delivery sheath has a radiopaque zone at its distal end. The tip is radiopaque, too. Proximal and distal to the loaded stents are radiopaque markers. Prior to deployment the shipping lock (Figure 3) must be removed and discarded.

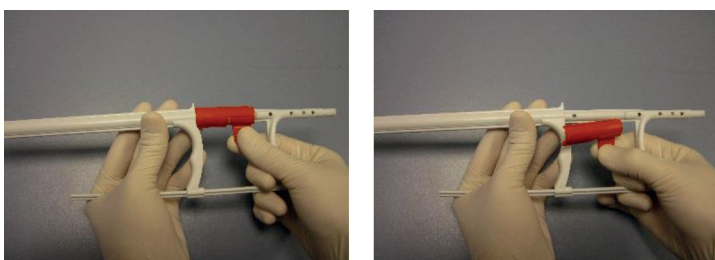


Figure 3 Handling of shipping lock

Content:

| Quantity | Material |
|----------|---|
| 1 | Peripheral Vascular Self Expanding Stent System |
| 1 | Instruction for Use |

Recommended storage

1. Keep in a cool, dark and dry place.
2. Use immediately after the sterile package is opened.
3. Refer to the symbol legend at the end of this document.

Disposal instructions

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Indications

The Finebent is intended for primary stenting of de-novo or restenotic lesions of the peripheral arteries.

Contraindications

Generally, contraindications to PTA are also contraindications for stent placement. Contraindications include, but are not limited to:

- Patients with highly calcified lesions resistant to PTA.
- Patients with a target lesion with a large amount of adjacent acute or subacute thrombus.
- Patients with Hyper-coagulopathy.
- Patients with stenosis or occlusion where lesion crossing with guide wire is not possible.
- Patients with fresh, soft thrombotic or embolic material.
- Patients with asymptomatic stenosis (Fontaine-Stage I).

Warnings and precautions

1. The Finebent is supplied sterile and is intended for single use only. DO NOT resterilize and/or reuse the device.
2. DO NOT use if pouch is opened or damaged.
3. DO NOT use the stent system after the end of the month indicated by the “Expires” date specified on the package.
4. Persons with allergic reactions to nickel titanium (nitinol) alloy may suffer an allergic response to this implant.
5. DO NOT use with ETIODOL™ or Lipiodol contrast media.
6. DO NOT expose the stent system to organic solvents (e.g. alcohol).
7. The stent is not designed for repositioning or recapturing.
8. Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures.
9. This medical device may be used only by physicians skilled in percutaneous transluminal angioplasty.
10. Prior to use, the packaging and product should be inspected for signs of damage. DO NOT use if packaging is damaged.
11. DO NOT use agents containing organic solvents or oleaginous contrast media. Contact with these agents may lead to damage of the product.
12. The Finebent should be handled carefully. Prior to use inspect the Finebent carefully for bends, kinks, or other damage. DO NOT use a damaged Finebent.
13. Confirm the compatibility of the product diameter and length with the introducer sheath and guide wire prior to use.
14. Since serious complications might arise when using this Self Expanding Stent System, operation should be done in a medical institution where emergency procedures can be executed
15. This Finebent can only be inserted with the use of a guide wire [Insertion of this device alone may lead to damage to the vascular wall or perforation of vessels.]
16. The guide wire must be completely advanced to reach towards the end of the vessel containing the lesion to be treated. [If guide wire is not completely advanced to the end, it may loosen from the guide wire lumen and it may even lead to damage to the vascular wall or perforation of vessels.]
17. If the guide wire is displaced from the guide wire lumen during operation, remove the device and reinsert the guide wire.

18. If abnormal or strong resistance is experienced during the operation the cause for such abnormality or resistance should be verified and appropriate measures should be performed before proceeding [If such abnormality or resistance is ignored and excessive force is applied, it may lead to damage of the vessels or to the device shaft breaking and remaining inside the body]
19. During usage, the Self Expanding Stent System shaft should be replaced if any, break or kink in the shaft occurs. [If the product continues to be used and such occurrence is ignored, suction may fail or the product shaft may be damaged and remain inside body.]
20. If a great resistance is encountered during insertion, movement, or pulling out of the Finebent, it should be verified that the guide wire is not tangled. If so, the tangling of the guide wire lumen of this device is short, the guide wire may wind around the device shaft.
21. Due to the lack of conductivity of twist forces, the device shaft should not be twisted [If twisted, the device shaft may be damaged and then remain inside the body.]
22. This device should not be unreasonably inserted into or swiftly pulled out from lesions with highly tortuous vessels, bifurcated lesions, or calcified lesions. [The shaft at the distal end may then kink or be damaged, leading to vascular damage.]
23. Precaution should be taken to prevent any damage to the device by other equipment (such as scalpels, blades or scissors). DO NOT use a damaged device.
24. During the usage of this device, the temperature, blood pressure, pulse, and respiration of patients should be monitored. In case of any abnormality, the procedure should be stopped or appropriate measures taken based on the physician's judgment.
25. Refer to the instructions supplied with any interventional devices to be used in conjunction with the system for their intended uses, contraindications, warnings, precautions, and instructions for use.
26. Appropriate drug therapy (anticoagulant, vasodilator, etc.) should be administered to the patient according to standard protocols for percutaneous interventions before insertion of the Finebent.
27. The delivery device is not designed for use with power injection systems.
28. Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution.
29. Prior to stent deployment, remove slack (see marked area in fig. 4) from the stent system outside the patient.
30. DO NOT attempt to break, damage, or disrupt the stent after placement.
31. As under PTA normally bigger and/or longer sheaths are used, which remain normally for a longer time than during a standard diagnostic catheter, vascular complications can be caused (examination hematoma, arterial fistula, aneurysma spuria and arterial thromboses).
32. Retraction of the delivery device is not possible. An attempt must be made to remove the delivery device, which may make surgical intervention necessary. In the worst case this can lead to an occlusion and/or a cardiac infarct.

Recommended drug regimen

Patients should receive adequate anti-platelet and anticoagulation therapy as prescribed by their physicians.

Possible complications and adverse reactions

Potential complications associated with the use of peripheral stents may include, but are not limited to:

- Allergic/anaphylactoid reaction
- Amputation
- Aneurysm
- Angina/coronary ischemia
- Arterial occlusion/thrombus, near the puncture site
- Arterial occlusion/thrombus, remote from puncture site
- Arterial occlusion/restenosis of the treated vessel
- Arteriovenous fistula
- Arrhythmia
- By-pass Surgery
- Death related to procedure
- Death unrelated to procedure
- Drug reactions to antiplatelet drugs / contrast media
- Embolization, arterial
- Embolization, stent
- Fever
- Hematoma bleed, remote site
- Hematoma bleed, puncture site
- Hypotension/hypertension
- Incompatibility of the local anesthetics
- Intimal injury/dissection

- Ischemia/infarction of tissue/organ
- Local infection
- Malposition (failure to deliver the stent to the intended site)
- Pulmonary embolism
- Perforation or Dissection of the vessel
- Pseudo aneurysm
- Renal failure
- Radiopaque material induced nephropathy
- Restenosis
- Rupture of the retroperitoneum or an adjacent organ
- Septicemia/bacteremia
- Stroke / cerebrovascular events
- Vascular Complications (hematoma, arterial fistula, aneurysms and arterial thromboses)
- Vasospasm
- Venous occlusion/thrombosis, remote from puncture site
- Venous occlusion/thrombosis, near the puncture site
- Sepsis / infection
- Stent migration
- Stent fracture
- Stent misplacement

Directions for Use

Pre-Deployment Procedure

1. Inject Contrast Media
Perform an angiogram using standard technique.
2. Evaluate and Mark Target Site
Fluoroscopically evaluate and mark the target site, observing the most distal diseased or obstructed segment.
3. Select Stent Size
Measure the length of the target lesion or stricture to identify the appropriate length of stent required. Ensure that the stent is long enough to permit the area proximal and distal of the lesion or stricture to be covered by the stent.
Identify the diameter of the reference vessel (proximal and distal to the lesion or stricture). To ensure secure placement, refer to the stent size selection table for proper sizing scheme. Refer to product labeling for stent length.

| Stent Size Selection Table: Finebent | |
|---|------------------------------------|
| Reference Vessel Diameter | Unconstrained Stent Inner Diameter |
| 4.0–5.0 mm | 6.0 mm |
| 5.0–6.0 mm | 7.0 mm |
| 6.0–7.0 mm | 8.0 mm |
| 7.0–8.0 mm | 9.0 mm |
| 8.0–9.0 mm | 10.0 mm |
| 9.0–10.0 mm | 11.0 mm |

Table 1

4. Prepare the Finebent
 - a) Open the box and remove the pouch containing the stent system.
 - b) Carefully inspect the pouch for damage to the sterile barrier. Then, peel the pouch open and remove the tray containing the stent system. Extract the stent system from the tray and check the following:

- ii) Verify that the shipping lock (Figure 3) is still secure in the stent system handle.
- ii) Examine the stent system for any damage. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used.
- c) Visually inspect the distal end of the stent system to ensure that the stent is contained within the sheath. DO NOT use if the stent is partially deployed.
- d) Flush the inner lumen of the device with saline prior to use.
- e) Wipe the usable length portion of the stent system with gauze soaked with saline.

Stent Deployment Procedure

1. Insert Introducer Sheath and Guidewire
 - a) Gain access at the appropriate site utilizing a 6F (2.0 mm) (or larger) introducer sheath.
 - b) Insert a guidewire of appropriate length (see table) and diameter across the stricture to be stented via the introducer sheath.

| Recommended guide wire length table | |
|---|-------------------------------|
| Usable Catheter Length of delivery device | Recommended guide wire length |
| 120 cm | 300 cm |
| 80 cm | 260 cm |

Table 2

2. Dilate Stricture

If the physician deems that predilation is required, standard techniques (e.g. PTA balloon catheter) may be used. While maintaining site access with a guide wire, remove the PTA balloon catheter from the patient.

Caution: During dilation, DO NOT expand the PTA balloon such that dissection complication or perforation could occur.

3. Introduce the Finebent

- a) Advance the device over the guidewire through the sheath introducer.

Note: If resistance is met during stent system introduction, the system should be withdrawn and another system should be used.

Caution: Always use an introducer sheath for the implant procedure to protect the vasculature and the puncture site. A 6F (2.0 mm) (or larger) introducer sheath is recommended.

- b) Position the tip of the delivery device catheter past the target site.
- c) Pull back the delivery device until the distal and proximal ends of the stent are in position so that they are distal and proximal to the target site.



Figure 4 Slack in stent system

- d) Remove slack (see marked area in Figure 4) from the stent system held outside the patient.

Caution: Any slack in the stent system (outside the patient) could result in deploying the stent beyond the target site.

4. Deploy Stent

1. Verify that the distal and proximal stent ends are distal and proximal to the target site.
2. Confirm that the introducer sheath is secure and will not move during deployment.
3. Remove the shipping lock (Figure 2).
4. Hold the handle in one hand by grasping the device by placing the handle in the palm of your hand in a pistol like fashion

5. Leave your thumb bent and in a bent fixed position as in Figure 5.
6. It is important to maintain this position throughout the deployment of the device as a modification of this position will enhance the chance of operating the device in a syringe like fashion which may cause the deployment of the prosthesis to be more distal than optimal.
7. Please note that a modification of your thumb to a position of that in Figure 6 is contra indicated and should not be used.
8. With your hand firmly around the handle assembly, and your thumb in a cocked position, your index finger on the top of the first handle assembly as show in Figure 7 above and your middle and ring finger firmly resting on the middle assembly as shown in Figure 8 slowly pull back on the 1st trigger assembly with a firm non-jerking motion.
9. As the prosthesis begins to deploy you will have the tactile sensation of the outer sheath of the device slowing retracting to release the prosthesis.
10. Verify the position of the device using fluoroscopy
11. Continue retracting the outer tube by slowly pulling the first trigger of the handle
12. For longer prosthesis a second trigger assembly should be engaged in the same fashion as the first.
13. Once your index, middle, and ring finger are firmly on the handle assembly begin to deploy the second trigger.
14. Pull the second trigger of the handle until the stent is released completely
15. It is contraindicated to push the hand assembly or to try to reconstrain the stent while using this device and any attempt to do so may cause the stent to be placed in a less than optimal location.

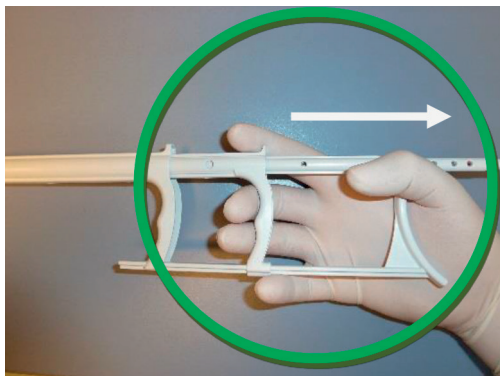


Figure 5



Figure 7

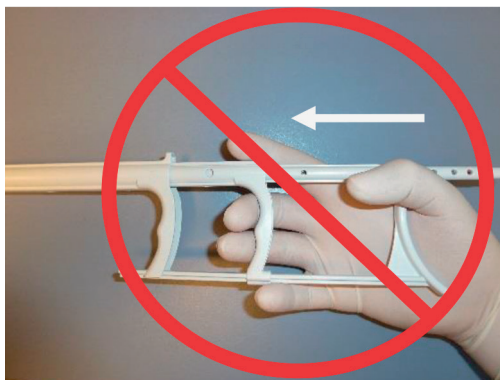


Figure 6

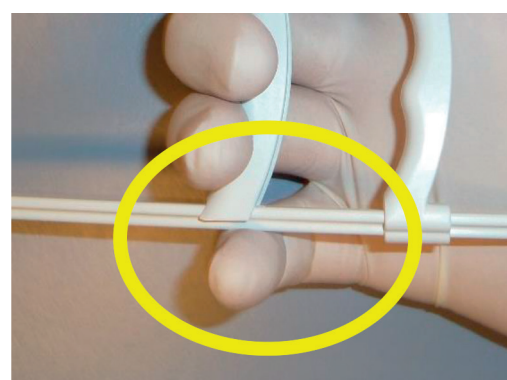


Figure 8

5. Post Stent Placement

- a) Remove the delivery device from the body.
- b) If additional stent-to-vessel apposition is desired, select a balloon catheter that matches the size of the reference vessel, but that is not larger than the stent diameter itself.
- c) Remove the guidewire and introducer sheath from the body.
- d) Close entry wound as appropriate.
- e) Discard the delivery device, guide wire, and introducer sheath.

Note: Physician experience and discretion will determine the appropriate drug regimen for each patient.

Magnetic Resonance Imaging (MRI Compatibility)

Non-clinical testing has demonstrated that the Finebent is MRI-compatible. Patients with the Finebent can be scanned safely, immediately after placement of this implant, under the following conditions:

- Static magnetic field of 3-Tesla or less
- Spatial gradient field of 720 Gauss/cm or less
- Maximum specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning.

In non-clinical testing, the Finebent produced a temperature rise of less than or equal to 1.4°C at a maximum specific absorption rate (SAR) of 3 W/kg for 15 minutes of scanning in a 3-Tesla MR system (Excite, Software G3.052B, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised to the area of interest is in the exact same area or relatively close to the position of the Finebent. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

Reuse precaution statement

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

References

The physician should consult recent literature on current medical procedures involving balloon dilatation, such as that published by international cardiologists' associations.

Warranty/Liability

The product and each component have been designed, manufactured, tested and packed with appropriate accuracy. The warning notices being contained in this Instruction of Use have to be considered particularly as an essential part of this clause. Accura grants a warranty on the products up to the mentioned "Best- Before-Date". A warranty exists only under the provision that the use of the product has been carried out in accordance with the Instruction of Use. Accura refuses each warranties or promises of a general usability for a certain purpose of the product. Accura is not liable for direct, indirect, incidental originated or secondary damages being caused by the product. With exception of a fault or of a considerable fault on the part of Accura a compensation of any damages which occur for the buyer will in no case be higher than the invoiced amount of the faulty product. The warranty contained in this clause considers and replaces the legal warranty for defects and compliance of the directives and excludes each other possibility of liability on the part of Accura howsoever this can be ascribed to the delivered products. This limitation of liability and warranty on the part of Accura does not gear towards to be in contradiction to compulsory regulations of applicable right. Should one of the clauses of the disclaimer of liability be abrogated from a responsible court or should it be declared to be in contradiction to the applicable right the effectiveness of the further clauses of this user contract remain unaffected and valid in the greatest possible extend. In this case the undersigned commit themselves to agree a new arrangement which complies at best with the entitled interests of Accura to restrict their liability or warranty. No one has the authority to oblige Accura for any warranty or liability concerning the product.









Available sizes with 80 cm shaft

| Lenght (mm) | 20 | 40 | 60 | 80 | 100 |
|---------------|-----------|-----------|-----------|-----------|-----------|
| Diameter (mm) | | | | | |
| 6 | SE602080F | SE604080F | SE606080F | SE608080F | SE601080F |
| 7 | SE702080F | SE704080F | SE706080F | SE708080F | SE701080F |
| 8 | SE802080F | SE804080F | SE806080F | SE808080F | SE801080F |
| 9 | SE902080F | SE904080F | SE906080F | SE908080F | SE901080F |
| 10 | SE102080F | SE104080F | SE106080F | SE108080F | SE101080F |
| 11 | SE112080F | SE114080F | SE116080F | SE118080F | SE111080F |

Available sizes with 120 cm shaft

| Lenght (mm) | 20 | 40 | 60 | 80 | 100 |
|---------------|-----------|-----------|-----------|-----------|-----------|
| Diameter (mm) | | | | | |
| 6 | SE602012F | SE604012F | SE606012F | SE608012F | SE601012F |
| 7 | SE702012F | SE704012F | SE706012F | SE708012F | SE701012F |
| 8 | SE802012F | SE804012F | SE806012F | SE808012F | SE801012F |
| 9 | SE902012F | SE904012F | SE906012F | SE908012F | SE901012F |
| 10 | SE102012F | SE104012F | SE106012F | SE108012F | SE101012F |
| 11 | SE112012F | SE114012F | SE116012F | SE118012F | SE111012F |

Graphical Symbols for Medical Device Labeling

| | | | |
|---|---|---|--|
|  Sterilized using ethylene oxide |  Lot number Batch number |  Manufacturer |  Do not re-use |
|  Use-by date |  Keep dry |  Keep away from sunlight |  Read instructions prior to use |
| | Storage Conditions: Keep in a cool, dry and dark place | | |

Manufacturer

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Germany



Distributor

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