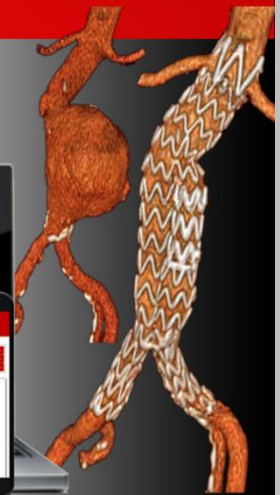


User's guide



EVARPLANNING

ENDOVASCULAR STENT GRAFT CONFIGURATION AND RENDERING



www.evarplanning.com

Version EVAR 1.9 – TEVAR 1.4

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Warning: this guide is based on version 1.9 of EVAR app and on version 1.4 of TEVAR app. Functions and features may change without notice. See website for update details.

1. INTRODUCTION

EVARplanning © is a computerized system dedicated to vascular surgeons, interventional radiologists and endovascular specialists. The system provides two web applications, for Endovascular Aortic Repair (EVAR) and Thoracic Endovascular Aortic Repair (TEVAR) respectively.

The aim of the apps is to help users choose the best prosthesis configuration on the basis of:

- the anatomical measurements, provided by the user*;
- the prostheses data: sizes, instructions for use (IFU) and recommendations, integrated in the apps;
- the user's preferences.

Most functions are intuitive and can be easily discovered while using the apps.
The main features and commands of the apps are briefly described in this guide.

* **Note:** the apps do not provide sizing tools. Users are supposed to enter data while or after taking measurements of the patient's CT scan by means of a proper vascular sizing software, according to standard methods of multiplanar reconstruction and vessel centerline-based measurement.

2. DISCLAIMER

The results of the planning provided by the applications are to be considered indicative for clinical use, subject to error, and therefore not definitive. We strongly recommend that the planning be verified with the supplier company before proceeding with the order.

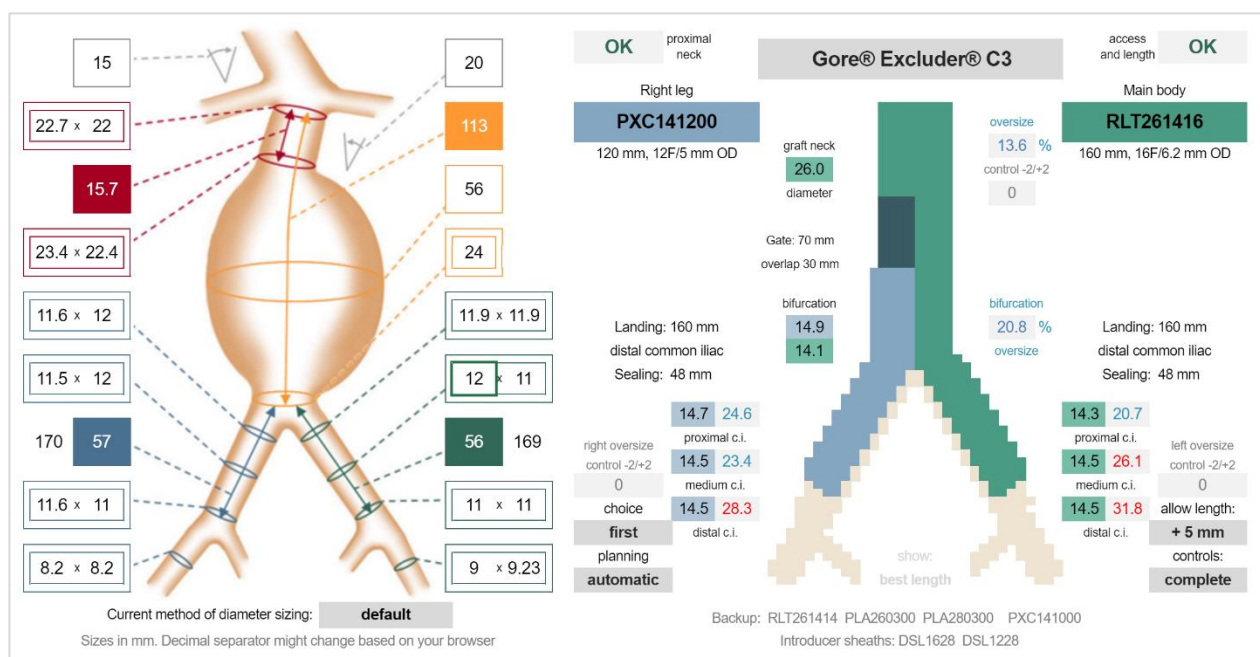
The author accepts no responsibility for the consequences of choice and use of the devices.

EVARplanning © has not been created or developed at the request of the manufacturers or retailers of the vascular prostheses; the former are relieved of any liability related to the use of the application.

Please reference appropriate product instructions for use for a more detailed list of indications, warnings, precautions and potential adverse events.

Products listed in the app may not be available in all markets.

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3. EVAR

3.1. STARTING THE APP

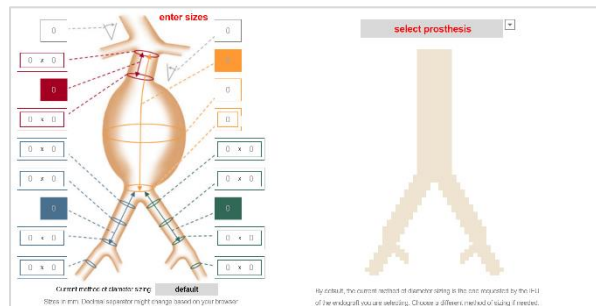
Connection to the Internet and free registration to EVARplanning © are needed to access the app. No download or software installation is required.

Note: We suggest using the app on your desktop/laptop computer. Mobile devices are not supported.

The app opens as in figure. All functions are included in one screen and appear step by step. You can simply start editing and make any changes to the plan. The data you enter will not be stored nor published online (nobody else will see your plan).

Note: Refreshing the page will reload the app, and no data will be saved. Please refer to Chapter 5 to save and reload results.

Note: Different browsers might slightly affect the app layout and speed.

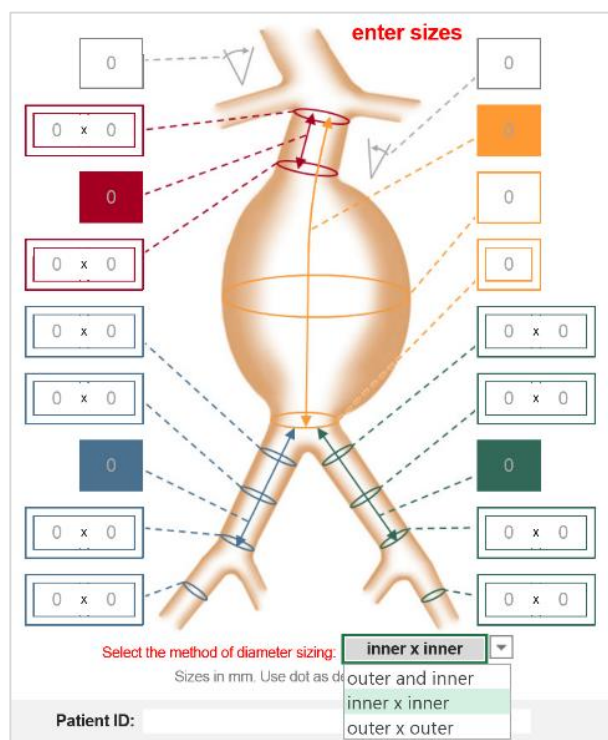


3.2. ENTERING THE ANEURYSM DATA

Enter the anatomical data of the patient into the fields on the left side of the app, around the aneurysm image. Follow the dotted lines to see which cell corresponds to each size.

Enter at least one diameter and length (mm) of the aortic neck and one diameter and length of each common iliac artery. Since the best results are achieved when measurements are more detailed, we suggest filling in the fields with two diameters of the aortic neck - at the very proximal end of the implantation site and at 10-15 mm distally, or more - and three diameters of each common iliac artery, at the proximal, medium and distal tracts.

Besides, the app allows you to enter two measurements at each level, and the average value will be automatically calculated.



Enter the aortic length (from proximal implantation site to bifurcation), the aneurysm diameter, and the bifurcation diameter (consider the maximum inner diameter in case of elliptical bifurcation). Fill in the external iliac artery fields with the values of the (minimum) access diameters.

Enter the alpha (suprararenal) and beta (infrarenal) angulation degrees, or leave them set to zero by default.

As an alternative to manual typing, the app allows users to import the sizes from 3mensio Vascular®, as well as to save and re-import the sizes after the first entering. Please refer to Chapter 5 to learn more.

Methods of measurement

Please take into consideration the method of measuring diameters (from inner wall to inner wall or from outer wall to outer wall) of the endograft that you are planning to use.

By default, the app follows the method requested by the IFU of the selected endograft. The size fields will show different borders based on the active method, to remind the user about the IFU request. Choose either *inner x inner* or *outer x outer* if needed.

By selecting *outer and inner* you can enter one value for the average outer diameter and one for the average inner diameter as well. This will allow you to choose among all types of endografts in real-time. The app will consider either the inner or the outer values depending on the IFU of the selected prosthesis.

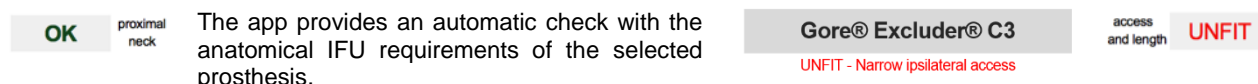
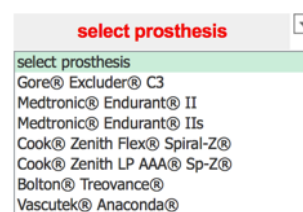
Demo mode: If the prosthesis type is selected before at least one diameter and length is entered at each side, default values will be automatically assigned, and a "demo sizes" message will be displayed. You can fill up or modify the values at any time during the planning.

3.3. SELECTING THE PROSTHESIS

Choose the graft you're planning to use. Available brands and types are listed in a drop-down menu, as in figure. Use the up and down arrow keys to scroll through the endografts.

Note: EVARplanning doesn't choose the graft type for you. The choice is based on the personal experience of the physician, who is supposed to know the main features of the prostheses. Presence of thrombus, calcification, tortuosity and other factors may affect this choice, or even the indication for endovascular treatment.

Note: You can change the graft type anytime during the planning. Measurement methods may vary based on the prosthesis type (see chapter 3.2).

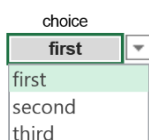


A green "OK", a red alert, or "UNFIT" message regarding the proximal neck and access/length compatibility with the graft type are displayed at the top of the app, near the prosthesis name.

3.4. AUTOMATIC PLANNING

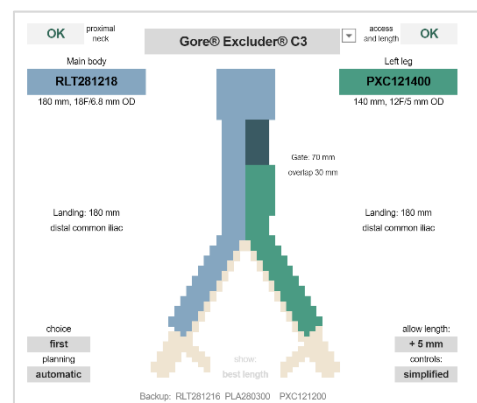
3.4.1. Choices

Once the endograft selection is done, the prosthesis configuration is displayed as in figure. By default, the app is set on automatic planning.

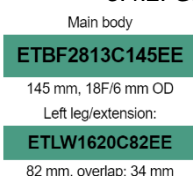


The best three configurations are available, based on EVARplanning's algorithm. The first choice is shown by default. Select "second" or "third" from the *choice* control, to see different solutions.

Note: The EVARplanning algorithm considers multiple parameters such as the oversize at different levels of the implant, the extent and diameter of the covered and uncovered iliac tracts, the effective sealing, the number of graft pieces, and many more. This kind of parametric evaluation is not easily accomplished without electronic assistance, and the reasons for a preferential configuration may sometimes be unclear. Opening the *complete* control (see 3.5) may help you understand the logics underneath.



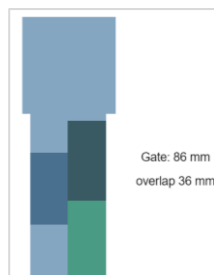
3.4.2. Graft codes and access data



The main body and the contralateral leg codes are displayed, as well as any additional extensions for both ipsilateral and contralateral side.

Indications about the graft length and the diameter of the corresponding deployment device (French and outer diameter size in mm) are also shown, and automatically matched with the values of the anatomical access sites. Alert or "unfit" messages are shown if necessary.

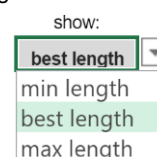
3.4.3. Lengths, overlaps, and landing zones



On each side, the app shows the length and the landing zone for the current prosthesis configuration. The landing zones and the overlapping parts of the grafts are schematically illustrated by the app.

If different lengths are available for a given configuration, because the overlap is variable, a command is enabled to control the displayed length, within the available range, from minimum length to maximum length. Other indications will vary accordingly. The drop-down menu is disabled if no length range is available.

Note: If the overlapping zones are variable, the best length is usually, but not always, the maximum length provided by that configuration, depending on the shape of arteries and grafts. The app shows the *best length* as default. When the maximum length is different on the right or left side, the command will be displayed in blue or green. Select max or min length as needed.



3.5. OVERSIZE CONTROL

controls:

simplified

simplified

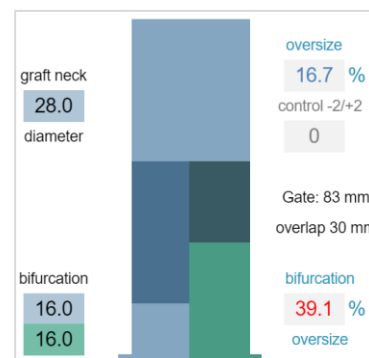
complete

By default, the app opens in a *simplified* view. By selecting *complete* in the “controls” drop down menu, access to the oversize control is allowed.

The oversize percentage of the prosthesis compared to the artery diameter is calculated at the neck level, at the aortic bifurcation and at different levels of the iliac axis.

The active oversize percentage is shown in blue, and it will turn red if IFU recommendations are not met.

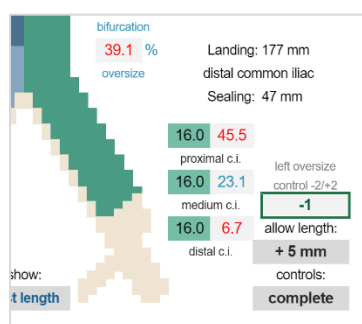
When different lengths are selected (see 3.4.3), the oversize values will vary accordingly.



3.5.1. Oversize correction

Interactions with oversize are possible at the neck level and/or distally at each side.

A slight or strong increment or decrement to standard oversize will be obtained – if available - by typing the following values into the oversize control box:



- 0 standard oversize (default value)
- 1 increase oversize slightly
- 2 increase oversize strongly
- 1 reduce oversize slightly
- 2 reduce oversize strongly

Note: If a not-standard choice is active, the selection remains displayed in the simplified view.

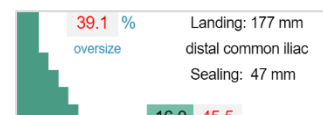
Note: “Standard” oversize may include an automatic amount of angulation-related neck oversize, based on prosthesis recommendations.

Note: Oversize control is available in both automatic and manual planning.

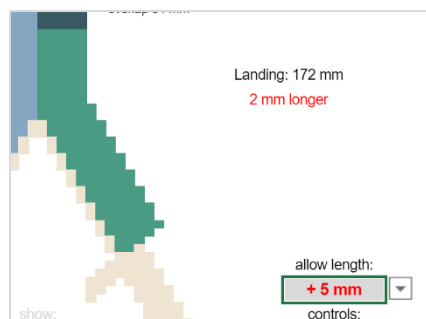
Note: Oversize at bifurcation level is calculated in one dimension, based on the maximum aortic diameter.

3.5.2. Sealing

Based on length, shape and diameters of the arteries and the grafts, an estimate of the effective sealing length is made, and displayed when complete control is active. The sealing indication will be shown in red if the IFU requirements about distal sealing are not met.



3.6. OVERLENGTH



The overlength function allows EVARplanning to find the best endograft configuration including solutions with a slightly longer landing than the iliac bifurcation length.

This might be very useful when a suitable graft is just few millimeters longer, and might work as a better alternative to an unsatisfactory more proximal landing.

The overlength function is automatic: when the app is started, the command is set to +5 mm by default. The user can disable the function and let EVARplanning accept only the exact length range, or even increase the chances up to +10 mm.

allow length:

+ 5 mm

exact only

+ 5 mm

+ 10 mm

We suggest that you have backups for the implant, and check the landing points by angiography. If preoperative measurements are confirmed, you may need to gently push the graft ahead during the deployment, to achieve a perfect alignment to the iliac bifurcation.

3.7. MANUAL PLANNING

When the *planning* control is set to “manual”, the following options become available.



3.7.1. Access side option



You may need to manually change the main body access side, choosing “right side” or “left side”. The app lets you try different configurations on each side, depending on the intended landing zones (see below). The endograft codes and all other results will automatically adjust based on selections.

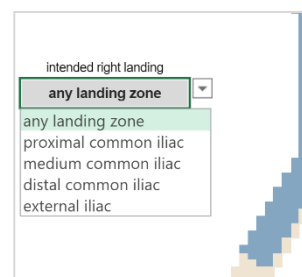
3.7.2. Landing zone selection

When manual planning is active, the intended landing zone command of each iliac axis (drop-down menu) is enabled.

You can just change the main-body access side (right or left), leaving both intended landing zone commands on *any landing zone*, to get a semi-automatic planning, or manually choose the zones as needed. The EVARplanning algorithm will provide the best configurations based on the active selections.

If the expected solution is not available, a different landing zone will be shown, in red color.

Three choices (first, second, third) are available in manual planning as well, to give users more options and interactivity in every case.



3.8. BACKUPS

As an additional result, the app provides a list of backup codes - the grafts you may need at the moment of the implantation, though you don't expect to use them.

Backup: ETBF2816C145EE ETCF2828C49EE ETLW1613C93EE ETLW1616C82EE ETEW1313C82EE
AU/convert: ETUF2814C102EE

4. TEVAR

4.1. STARTING THE APP

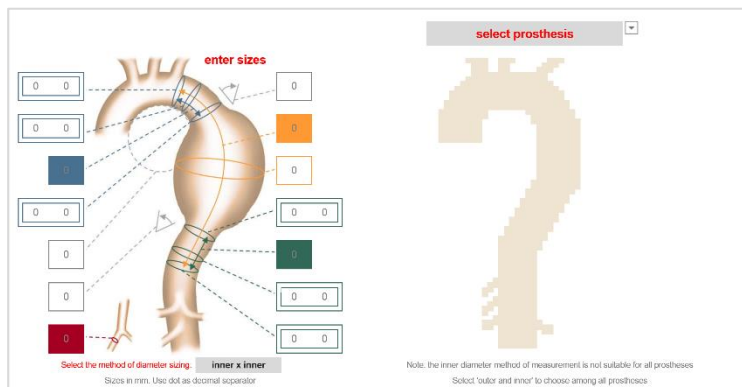
Connection to the Internet and free registration to EVARplanning © are needed to access the app. No download or software installation is required.

Note: We suggest using the app on your desktop/laptop computer. Mobile devices are not supported.

The app opens as in figure. All functions are included in one screen and appear step by step. You can simply start editing and make any changes to the plan. The data you enter won't be stored nor published online.

Note: Refreshing the page will reload the app, and no data will be saved. Please refer to Chapter 5 to save and reload results.

Note: Different browsers might slightly affect the app layout and speed.



4.2. ENTERING THE ANEURYSM DATA

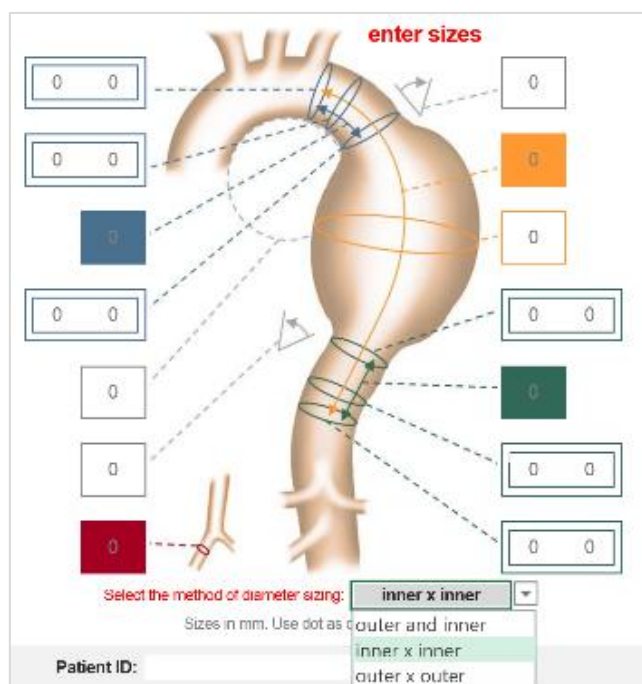
Enter the anatomical data of the patient into the fields on the left side of the app, around the aneurysm image. Follow the dotted lines to see which cell corresponds to each size.

Enter at least one diameter and length (mm) of the proximal implantation site (proximal neck) and one diameter and length of the distal aortic implantation site (distal neck). Since the best results are achieved when measurements are more detailed, we suggest filling in the fields with three diameters of each aortic neck.

Besides, the app allows you to enter two measurements at each level, and the average value will be automatically calculated.

Enter the intended covered aortic length (including both proximal and distal implantation sites), the aneurysm diameter, and the radius of curvature along the entire length of aorta intended to be treated (i.e. the aortic arch radius may be required to be greater than 20 mm). Fill in the (minimum) access vessel diameter.

Enter the proximal and distal angulation degrees, or leave them set to zero by default.



As an alternative to manual typing, the app allows users to import the sizes from 3mensio Vascular®, as well as to save and re-import the sizes after the first entering. Please refer to Chapter 5 to learn more.

Methods of measurement

Please take into consideration the method of measuring diameters (from inner wall to inner wall or from outer wall to outer wall) of the endograft that you are planning to use. By default, the app follows the method requested by the IFU of the selected endograft. The size fields will show different borders based on the active method, to remind the user about the IFU request. Choose either *inner x inner* or *outer x outer* if needed.

By selecting *outer and inner* you can enter one value for the average outer diameter and one for the average inner diameter as well. This will allow you to choose among all types of endografts in real-time. The app will consider either the inner or the outer values depending on the IFU of the selected prosthesis.

Demo mode: If the prosthesis type is selected before at least one diameter and length is entered at each side, default values will be automatically assigned, and a “demo sizes” message will be displayed. You can fill up or modify the values at any time during the planning.

4.3. SELECTING THE PROSTHESIS

Choose the graft you're planning to use. Available brands and types are listed in a drop-down menu, as in figure.

Note: EVARplanning doesn't choose the graft type for you. The choice is based on the personal experience of the physician, who is supposed to know the main features of the prostheses. Presence of thrombus, calcification, tortuosity and other factors may affect this choice, or even the indication for endovascular treatment. You can change the graft type anytime during the planning.

The app provides an automatic check with the anatomical IFU requirements of the selected prosthesis.

select prosthesis

select prosthesis
 Gore® TAG®
 Medtronic® Valiant Captivia®
 Cook® Zenith Alpha®
 Cook® Zenith dissection®
 Cook® Zenith TX2®
 Bolton® Relay plus®
 Bolton® Relay NBS plus®

Proximal neck: A green "OK", a red alert, or "UNFIT" message regarding the proximal and distal necks and access/length compatibility with the graft type are displayed at the top of the app, near the prosthesis name.

Distal neck: OK
Access and size: UNFIT

4.4. SELECTING THE LANDING ZONES

Select the intended proximal landing zone, based on Ishimaru classification, and the distal landing zone, similarly (drop-down menu).

SELECT PROXIMAL LANDING ZONE

SELECT PROXIMAL LANDING ZONE
 Z0: overstenting of all supra-aortic trunks
 Z1: distal to IA (LSA+LCA overstenting)
 Z2: distal to LCA (LSA overstenting)
 Z3: distal to the left subclavian artery
 Z4: descending thoracic aorta

the image to proportionally fit to the real anatomical situation, but they do not affect the prosthesis configuration.

proximal landing: Z3: distal to the left subclavian artery
 distal landing: Z4: proximal to the celiac trunk

+/- mm

20

Note: If the proximal landing zone is selected between Z0 and Z3, the distal end of the graft depends on the selected length (see 2.2).

The distal landing zone selection becomes relevant only if the proximal is set on Z4, or if the intended length overpasses the celiac trunk origin.

Default vessels positions are optionally editable in order to allow the image to proportionally fit to the real anatomical situation, but they do not affect the prosthesis configuration.

Default vessels position (mm from aortic valve)				
IA	80	CT	500	
LCA	120	SMA	532	
LSA	152	RA	564	572

4.5. SELECTING THE CONFIGURATION

Next selections allow you to set up the prosthesis configuration by choosing between single component (one piece) or two overlapped components (two pieces).

SELECT

SELECT
 one piece
 two pieces

If a single component configuration is selected, a further length option is available (drop-down menu), allowing the app to search only for a graft exactly as long as the intended length or accepting a shorter or a longer graft.

length range: SELECT

SELECT
 shorter
 exact
 longer

Note: If a two-pieces configuration is selected, the length option will slightly change its function, since exact length is usually obtainable by varying the overlap within the same configuration. The three length selections will now provide the choice of different two-pieces configurations - if available - with a shorter, longer or medium ("exact") range of length.

4.6. RESULTS AND CONTROLS

Once the previous selections are made, the prosthesis configuration is displayed as in figure.

4.6.1. Graft codes and access data

Single component or two pieces (proximal and distal components)

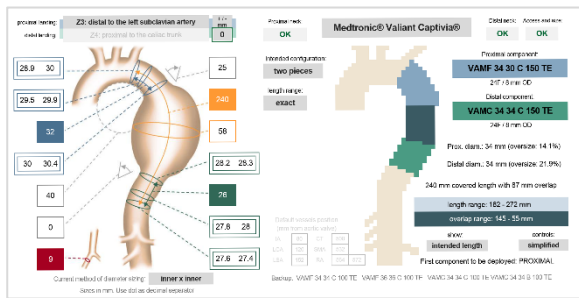
Medtronic® Valiant Captivia®

SELECT
 one piece
 two pieces

length range: SELECT

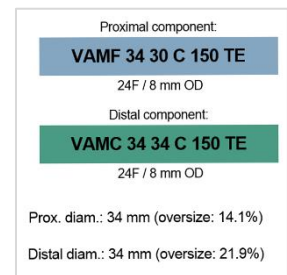
SELECT
 shorter
 exact
 longer

9



codes are displayed, based on the intended configuration and the availability of suitable graft diameters and lengths. A different solution is suggested if the intended configuration is not possible.

Indications about the diameter of the corresponding deployment device (French and outer diameter size in mm) are also shown, and



automatically matched with the values of the anatomical access sites. Alert or "unfit" messages are shown if necessary.

4.6.2. Length and overlap

All configuration data are shown on the right side of the image: diameters, oversizes, working lengths and overlaps. If overlapping zones are variable, ranges of length and ranges of overlap will be displayed. Results will appear in red if IFU requests are not met.

The image will represent max or min length depending upon selection (see 2.6.3)

If the length differs from the initial intention, the mismatch is displayed (it will be shown in red if > 20 mm), and a message will remind about checking differences in arterial diameter at the new landing site.

4.6.3. Length view option

show:

intended length

min length

intended length

max length

Landing zones and overlapping parts of the grafts are schematically illustrated. If different lengths are available for a given configuration, the image shows the minor or the maximum length, depending on the active selection. The drop-down menu is not displayed if no length range is available.

4.7. OVERSIZE CONTROL AND ADVANCED OPTIONS

controls:

simplified

simplified

complete

By default, the app opens in a *simplified* view. Selecting *complete* in the "controls" drop down menu, access to the advanced options is allowed.

4.7.1. Oversize controls

standard

reduce strongly

reduce slightly

standard

increase slightly

increase strongly

The oversize percentage of the prosthesis compared to the artery diameter is calculated at the proximal and distal implantation sites, and shown with respective diameters. The number turns red if IFU recommendations are not met.

Interactions with oversize are possible at

both sites, by a slight or strong increment or decrement (drop-down menu). If a not-standard choice is active, the selection remains displayed in the simplified view also.

Note: "Standard" oversize may include an automatic amount of angulation-related neck oversize, based on prosthesis recommendations.

4.7.2. Proximal design, tapered grafts and deployment controls

Further selections in the advanced options drop-down menu let the user choose the proximal graft design - bare stent or not -, include or exclude the use of tapered components, or choose the sequence of deployment, if needed, by restricting the possible two-pieces configurations to those with a proximal-first or a distal-first deployment. Selecting the "indifferent" option, no restriction will be active and all configurations will be considered.

Not-standard choices will remain displayed in the simplified view also.

optimize for:

aneurysm

prox oversize:

increase slightly

dist. oversize:

standard

prox design:

indifferent

tapered:

include tapered

deployment:

indifferent

4.7.3. Aneurysm/Dissection option

The first control in the advanced options menu allows you to optimize the app for use in aneurysm or dissection.

Most of the prostheses used for aneurysm are also indicated in cases of aortic dissection (AD) or intramural hematoma (IMH), though graft selection criteria may change.

Select "Dissection" when TEVAR is planned in AD or IMH. If selected prosthesis is not compatible, an "unfit" alert will be shown. If applicable, the standard graft configuration will change according to eventual different IFU recommendations and oversize ranges for AD. The app allows you to add further corrections by a slight/strong oversize increment/decrement, as previously described.

Note: Consider the size of non-dissected aorta proximal to the primary entry tear – usually the tract between left carotid and left subclavian artery - as the proximal implantation site (proximal neck). If you do not intend to consider distal diameter for graft selection in dissections, you may want to copy the proximal diameter into distal diameters, or add half of the false lumen diameter to the true lumen diameter size. Intended covered length may also change based on physician's choice, as well as the indication for adding a distal bare stent. In case of two-pieces intended configuration, the proximal device must be deployed first.

Note: Atherosclerotic and post-traumatic lesions usually require higher oversize rates, and "Aneurysm" selection.

Proximal neck: **OK** Cook@ Zenith dissection® Distal neck: Access and size: **OK** **OK**

Intended configuration: **one piece** Single component: **ZDEG-P-34-154-PF**

length range: **longer** 20F / 7.7 mm OD

optimize for: **dissection** Prox. diam.: 34 mm (oversize: 14%)

prox oversize: **standard** Distal diam.: 34 mm (oversize: 21.7%)

dist. oversize: **standard** Tot. length: 154 mm length mismatch: 4 mm

prox design: **indifferent** Consider length for primary tear coverage

tapered: **include tapered** Add one or more distal bare stents*

deployment: **indifferent** show: **intended length** controls: **complete**

Default vessels position (mm from aortic valve)

JA	58	CT	308
LCA	120	SMA	132
LSA	131	RA	364 372

*DISTAL BARE STENTS: GZSD-36-82-2 GZSD-36-123-2 GZSD-36-164-2 GZSD-46-82-2 GZSD-46-123-2 GZSD-46-164-2

4.8. BACKUPS

As an additional result, the app provides a list of backup codes - the grafts you may need at the moment of the implantation, though you don't expect to use them.

Backup: VAMF 32 32 C 200 TE VAMF 32 32 C 100 TE VAMF 34 34 C 100 TE VAMC 32 32 B 100 TE

5. SAVE AND RELOAD

EVARplanning allows users to easily save sizes and planning results, and to quickly reload the measurements into the app whenever needed. These functions are available for both EVAR and TEVAR apps.

5.1. SAVING MEASUREMENTS

1. Fill up the fields of the app with the measurements. You can do it manually, or by quickly importing them from 3mensio Vascular®, or back from your archive, using the **SmartCode** (see below).
2. Once the sizes are entered, a “Sizes” box is displayed at the bottom of the app. Click on the box and copy (Ctrl+C on Windows, or Cmd+C on MAC).
3. Paste (Ctrl+V or Cmd+V) into the first column of **My EVARplanning Archive**, a Microsoft® Excel file that you can download for free from the EVARplanning website and keep it as an archive of your cases. All sizes are saved into the file, and ready to be easily reloaded, if needed.

The screenshot displays the EVARplanning app interface. On the left, a 3D model of a patient's aorta is shown with various measurement points labeled with dimensions (e.g., 22 x 21.5, 15, 22.5 x 22, 11 x 10.7, 11.6 x 11, 55, 12 x 11.6, 9 x 9, 112, 59, 25, 12 x 12.5, 11.5 x 12, 63, 12 x 12.4, 9 x 9). A 'select prosthesis' button is visible on the right. Below the model, there is a 'Patient ID' field (John Doe), a 'Date' field (1/31/2016), and an 'Export (Ctrl-C)' button. A '3mensio SmartCode' field is also present. At the bottom, a 'Sizes' box is highlighted with a green arrow and the text 'Ctrl+C'. Below the app interface, a screenshot of an Excel spreadsheet is shown, with the 'Sizes' column highlighted and a green arrow pointing to it with the text 'Ctrl+V'.

Patient ID	Date	Export SmartCode	alpha	neck	neck	neck	neck	neck	prox	prox	mediu	mediu	right	distal	distal	right	e	right	e	beta	a	orta	max	e	carrel	proxim	proxim	mediu	mediu	left	co
John Doe	2016-01-31		0	22	21,5	15	22,5	22	11	10,7	11,6	11	55	12	11,6	9	9	0	112	59	25	12,5	12	12	11,5	63					

5.2. SAVING THE PLANNING

1. Once you finish planning with EVARplanning, simply click and copy (Ctrl+C on Windows, or Cmd+C on MAC) the “Plan” box at the bottom of the app.
2. Paste (Ctrl+V or Cmd+V) into the first column of **My EVARplanning Archive**. The whole plan is saved in the archive, including sizes and the endograft configuration data. You will be able to quickly reload the sizes into the app and change the plan, whenever needed.

