

"BUILD-A-GUIDEWIRE" PROGRAM

Shorten Guidewire development cycles with the TechDevice "Build-A-Guidewire" Program. A variety of stock and custom materials can be used to create a guidewire with the feel you require.

Follow the step by step process on this questionnaire to provide as much information about the product requirements as possible. If you have prints available, please attach them to this sheet and complete the information not available on the print. If tolerances are required for specific dimensions, please note them. TechDevice will use standard tolerances where they are not noted otherwise.

If your guidewire construction and indication fall within one of our 510(k)'s, time to market could be reduced.

Step 1. Choose your length in centimeters with a tolerance of +/- 1 cm.

Step 2. Choose your diameter in increments of .001" between .014" and .038"

Step 3. Choose one of these constructions.

- Fixed core with round or flat wire coil full length. The core is welded to the coil at several points in this construction.
- Moveable core with round or flat wire coil full length.
- Solid core with coiled tip.
- Solid core with tapered end(s).
- Jacketed core wire with coil tip.
- Jacketed wire with pebax tip.

Step 4. Select the core material:

304 Stainless Steel Light Oxide Nitinol Dark Oxide Nitinol Other: _____

Include tensile information and material specifications if available _____

Step 5. Taper Type:

Print of tapered core is available Yes No If yes, go to Step 6.

Straight tip _____ J tip (specify size) _____

Single taper _____ or multiple taper _____

Floppy _____ Super floppy _____ Stiff _____

Core starting diameter _____

Length of taper _____

Additional comments _____

6/15/10

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See reverse side for detailed questionnaire.

FDA
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Step 6. Choose the coil material:

304V___ Platinum___ Paliney___ Gold Plated Tungsten___ Other_____

Comments_____

Step 7. Coil Wire Diameter_____

Step 8. Coil ID _____

Step 9. Coil OD _____

Step 10. Coil Length _____ Note pitch, spacing or end cut requirements_____

Step 11. Coating: ___Yes ___No

If yes, what type of coating?

PTFE___ Color___ Hydrophilic___ Other_____

Area to be coated: _____

Step 12. Is a jacket required? ___Yes ___No

If Yes, what type of jacket?

PTFE___ Recovered Wall___ Color_____

Other Material_____ Wall_____ Color_____

Step 13. How do you want the wire packaged?

Bulk non-sterile___ hooped___ pouched___ labeled___ boxed___ sterilized___

Step 14. Indications:

___Peripheral Vasculature, ___Gastroenterology, ___Renal, ___Urology, ___Gynecology,

___Radiology, ___Neurology, ___Other_____

Step 15. Provide product stage and contact information.

Product Stage:

Is this order for: ___prototypes ___animal trials ___clinical trials ___production

Product Stage: ___PMA ___510(k) ___existing product

Contact Information:

Company Name: _____ Project Name: _____

Address: _____

Contact: _____ Title: _____

Phone Number: _____ E-mail: _____

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