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AMENDMENT 1
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Sterile single-use intravascular introducers, dilators and guidewires

AMENDMENT 1

Introducteurs, dilatateurs et guides intravasculaires stériles non réutilisables

AMENDEMENT 1

Reference number
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This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

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8.6

Designate the existing NOTE as NOTE 1 and add the following new NOTE:

"NOTE 2 This requirement also applies for guidewires with polymer jackets."

9.3.3

Replace "minimum force at break" with "peak tensile force".

F.2.1

Replace "(see 8.2)" with "(see 8.4)".

F.3.3

Add in between the first and second sentence:

"Ensure that the coils are pushed towards the distal end during testing and not forced towards the proximal end."

Add after the last sentence in F.3.3

"Care should be taken not to apply pull force on the coils that is not clinically relevant. Hold in proximal (backend) and push coils forward when operating."

G.2.1

Replace "(see 8.2)" with "(see 8.5)".

H.2.2

Replace the text with the following:

"**Split tapered clamp,** with closed diameter of 0,02 mm less than the minimum diameter of guidewire to be tested, or alternative arrangement."

Figure H.1

Delete the figure.

I.3.2

Add the following sentence at the end of the subclause:

"Based on risk assessment, the manufacturer can apply slower test speed in order to reach the target force."