



California Device Recall Information Sheet

Angiodynamics, Inc. Recalls Mini Stick Max 4f Due To Non-Conformance Between The Guidewire And Introducer Hub

Recall Date	Product Description	Recalling Firm	Recall Reason
3/27/2024	Mini Stick Max 4f X 10 Cm Std .018 Ss/Pd Echo 2.75" Pg Used for the percutaneous introduction of a guidewire into the vascular system. Catalog Number: 45-749	ANGIODYNAMICS, INC. Queensbury, New York	Non-conformance may prevent the guidewire from passing through the introducer hub during a surgical procedure. The inability of the guidewire to pass through the introducer is due to the presence of voids in the internal lumen of the sheath hub, potential risk of the non-conformance is a delay in procedure, wherein the user may need to exchange the sheath to complete the case.
3/27/2024	Mini Stick Max 4f X 10 Cm Std .018 Ni/Tu Echo 2.75" Pg Used for the percutaneous introduction of a guidewire into the vascular system. Catalog Number: 45-750	ANGIODYNAMICS, INC. Queensbury, New York	Non-conformance may prevent the guidewire from passing through the introducer hub during a surgical procedure. The inability of the guidewire to pass through the introducer is due to the presence of voids in the internal lumen of the sheath hub,

			potential risk of the non-conformance is a delay in procedure, wherein the user may need to exchange the sheath to complete the case.
3/27/2024	<p>Mini Stick Max 4f X 10 Cm Stiff .018 Ss/Ss Echo 2.75" Pg Used for the percutaneous introduction of a guidewire into the vascular system. Catalog Number: 45-751</p>	<p>ANGIODYNAMICS, INC. Queensbury, New York</p>	Non-conformance may prevent the guidewire from passing through the introducer hub during a surgical procedure. The inability of the guidewire to pass through the introducer is due to the presence of voids in the internal lumen of the sheath hub, potential risk of the non-conformance is a delay in procedure, wherein the user may need to exchange the sheath to complete the case.
3/27/2024	<p>Mini Stick Max 4f X 10 Cm Stiff .018 Ss/Pd Echo 2.75" Pg Used for the percutaneous introduction of a guidewire into the vascular system. Catalog Number: 45-752</p>	<p>ANGIODYNAMICS, INC. Queensbury, New York</p>	Non-conformance may prevent the guidewire from passing through the introducer hub during a surgical procedure. The inability of the guidewire to pass through the introducer is due to the presence of voids in the internal lumen of the sheath hub, potential risk of the non-conformance is a delay in procedure, wherein the user may need to exchange the sheath to complete the case.

3/27/2024	<p>Mini Stick Max 4f X 10 Cm Stiff .018 Ni/Tu Non-Echo 2.75" Pg Used for the percutaneous introduction of a guidewire into the vascular system. Catalog Number: 45-762</p>	<p>ANGIODYNAMICS, INC. Queensbury, New York</p>	<p>Non-conformance may prevent the guidewire from passing through the introducer hub during a surgical procedure. The inability of the guidewire to pass through the introducer is due to the presence of voids in the internal lumen of the sheath hub, potential risk of the non-conformance is a delay in procedure, wherein the user may need to exchange the sheath to complete the case.</p>
3/27/2024	<p>Mini Stick Max 4f X 10cm Stiff .018 Ni/Tu Echo 1.6" Pg Used for the percutaneous introduction of a guidewire into the vascular system. - Catalog Number: 45-781</p>	<p>ANGIODYNAMICS, INC. Queensbury, New York</p>	<p>Non-conformance may prevent the guidewire from passing through the introducer hub during a surgical procedure. The inability of the guidewire to pass through the introducer is due to the presence of voids in the internal lumen of the sheath hub, potential risk of the non-conformance is a delay in procedure, wherein the user may need to exchange the sheath to complete the case.</p>

Recall Class	Product Identification	Distribution	Affected Dates
II	<p>Mini Stick Max 4f X 10 Cm Std .018 Ss/Pd Echo 2.75" Pg UDI: 15051684022927 UPN: H965457491 Lot Number: 5805056</p>	0 Units in California	January, 2024 and prior

II	Mini Stick Max 4f X 10 Cm Std .018 Ni/Tu Echo 2.75" Pg UDI: 15051684022934 UPN: H965457501 Lot Number: 5784035 5784036 5784136 5787837 5788554 5788555 5789978 5790448 5790449 5791589 5791590 5791591 5797460 5797461 5798838 5799613 5799623 5800399 5804390 5806116	396 Units in California	January, 2024 and prior
II	Mini Stick Max 4f X 10 Cm Stiff .018 Ss/Ss Echo 2.75" Pg UDI: 15051684022941 UPN: H965457511 Lot Number: 5789981 5789983 5791592 5791595 5795873 5797462	0 Units in California	January, 2024 and prior
II	Mini Stick Max 4f X 10 Cm Stiff .018 Ss/Pd Echo 2.75" Pg UDI: 15051684022958 U UPN: H965457521 Lot Number: 5805057 5806119	0 Units in California	January, 2024 and prior
II	Mini Stick Max 4f X 10 Cm Stiff .018 Ni/Tu Non-Echo 2.75" Pg UDI: 15051684023054 UPN: H965457621 Lot Number: Lot: 5788541 5789982 5791594 5794608 5797468 5798845	58 Units in California	January, 2024 and prior
II	Mini Stick Max 4f X 10cm Stiff .018 Ni/Tu Echo 1.6" Pg UDI: 15051684023238 UPN: H965457811 Lot Number: 5791593 5794613 5797470	0 Units in California	January, 2024 and prior

For additional information, please visit the FDA website [Catalog Number 45-749](#), [45-750](#), [45-751](#), [45-752](#), [45-762](#), [45-781](#)

